

From: [Therapeutic Goods Administration \(TGA\)](#) on behalf of tga.no-reply@govcms.gov.au
To: [TGA FOI](#)
Subject: FOI request: 301
Date: Friday, 28 February 2025 9:32:28 AM

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Submitted on Fri, 2025-02-28 09:23

Submitted by: Anonymous

Submitted values are:

Who this FOI request is for

This FOI request is for:
Myself

Your details

Are you an:

s47

Honorific

s47F

Name

s47F

Contact email address

s47F

@s47

Preferred contact number

s47F

s47

Documents requested

Under the FOI Act 1982, I seek access to copies of:

Orphan Drug Designation application for Sodium Oxybate for the treatment of narcolepsy, by the sponsor Reach Pharmaceuticals Pty Ltd approved 20 Nov 24, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.

Orphan Drug Designation application for sebetralstat for the treatment of Hereditary

angioedema, by the sponsor JACE Pharma Pty Ltd approved 2 Aug 2024, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.

From date

01/01/2023 - 12:00am

To date

28/02/2025 - 12:00am

Personal information of third parties in documents

Can we remove the personal info of any third parties from the documents

Yes

Can we share your details with any relevant third parties

No

From: [TGA FOI](#)
To: s47F@ s47
Cc: [TGA FOI](#)
Subject: FOI 25-0171 - Notification of receipt [SEC=OFFICIAL]
Date: Tuesday, 4 March 2025 3:25:20 PM
Attachments: [image001.jpg](#)

Dear s47F

FREEDOM OF INFORMATION REQUEST – NOTIFICATION OF RECEIPT

I am writing to notify you that the Therapeutic Goods Administration (Department of Health and Aged Care) has received your request for access to documents under the *Freedom of Information Act 1982* (FOI Act) as follows:

‘Orphan Drug Designation application for Sodium Oxybate for the treatment of narcolepsy, by the sponsor Reach Pharmaceuticals Pty Ltd approved 20 Nov 24, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.

Orphan Drug Designation application for Sebetralstat for the treatment of Hereditary angioedema, by the sponsor JACE Pharma Pty Ltd approved 2 Aug 2024, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.’

The timeframe for your request is from 1 January 2023 to 28 February 2025.

Under section 15(5)(b) of the FOI Act, the agency has 30 calendar days from the date your request was received in which to provide a decision in response to your request for access. A decision is currently due on or before **30 March 2025**. Due to the statutory processing time afforded under the FOI Act in which to provide you with a decision in relation to your FOI request, we would be grateful if you could please monitor your emails periodically for updates regarding your request.

Where there is requirement to undertake consultation with affected third parties, this timeframe is extended by a further 30 days. It may also be extended in certain circumstances, including with your agreement or where the Department applies to the Office of the Australian Information Commissioner for an extension.

Unless you advise otherwise, draft and duplicate documents, Commonwealth employee names and contact details of staff below Senior Executive Service level, internal group email addresses and mobile telephone numbers of all staff will be excluded from the scope of your request under section 22(1)(a)(ii) of the FOI Act.

Disclosure Log Publication:

The TGA is required under section 11C of the FOI Act to publish on its website, or otherwise make available, documents released to an applicant in response to an FOI request, unless exceptional circumstances apply. The TGA publishes these documents on the FOI Disclosure Log at [FOI Disclosure Log | Therapeutic Goods Administration](#). You can find more information about the Disclosure Log at [OAIC FOI Guidelines | Disclosure Logs](#).

In addition, please note that if the decision maker decides that you are liable to pay a charge in relation to your request then this timeframe is extended pending payment of a deposit. You will be notified by the Department if you are liable to pay a charge and/or if third party consultation is required.

If you have any queries, please contact the FOI team on (02) 6289 4630, or via email at TGA.FOI@tga.gov.au.

Kind regards

s22

Freedom of Information

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
Address: PO Box 100, Woden ACT, 2606, Australia

E: TGAFOI@tga.gov.au

T: + 61 2 6289 4630

Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

From: Therapeutic Goods Administration (TGA) tga.no-reply@govcms.gov.au

Sent: Friday, 28 February 2025 9:32 AM

To: TGA FOI TGAFOI@health.gov.au

Subject: FOI request: 301

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Submitted on Fri, 2025-02-28 09:23

Submitted by: Anonymous

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Are you an:

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Name

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Contact email address

s47F @s47

Preferred contact number

s47F

s47


Documents requested

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From date

01/01/2023 - 12:00am

To date

28/02/2025 - 12:00am

Personal information of third parties in documents

Can we remove the personal info of any third parties from the documents

Yes

Can we share your details with any relevant third parties

No

From: s47F
To: TGA FOI
Subject: Re: FOI 25-0171 - Scope clarification [SEC=OFFICIAL]
Date: Tuesday, 18 March 2025 2:24:43 PM
Attachments: [image001.jpg](#)
[image002.jpg](#)

Dear s22

I confirm s47 do not require copies of all the papers submitted in support of the ODDs, provided the reference list is supplied.

Thank you

Kind regards

s47F

Get [Outlook for iOS](#)

From: TGA FOI
Sent: Tuesday, March 18, 2025 2:07:51 PM
To: s47F
Cc: TGA FOI
Subject: FOI 25-0171 - Scope clarification [SEC=OFFICIAL]
Dear s47F

I am writing further as an update and to seek clarification regarding the scope of your request, which is currently as follows:

'Orphan Drug Designation application for Sodium Oxybate for the treatment of narcolepsy, by the sponsor Reach Pharmaceuticals Pty Ltd approved 20 Nov 24, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.'

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The timeframe for your request is from 1 January 2023 to 28 February 2025.

For your consideration

The FOI team has now received documents following the formal search and retrieval process. Within the suite of documents are a large number (in excess of 50) medical papers and journal articles that were provided in support of an application, specifically an orphan drug designation application. I can confirm that these medical papers and journal articles have been listed as references within another document which has been retrieved from the line area for your request.

Should you seek access to these documents, the request may be considered too voluminous for the TGA to process. As such, I write to seek your consideration of omitting these medical papers and journal articles from the scope of your request.

We would be grateful for your response by **COB Thursday 20 March 2025** and we thank you for your time.

Please don't hesitate to contact the FOI team if you have any questions or if you would like to discuss this.

Kind regards

s22

Freedom of Information

Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care
 T: 02 6289 4630 | E: TGAFOI@health.gov.au
 PO Box 100, Woden ACT 2606, Australia
 Web: www.tga.gov.au

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The Department of Health and Aged Care 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: TGA FOI

Sent: Tuesday, 4 March 2025 3:25 PM

To: s47F @s47

Cc: TGA FOI

Subject: FOI 25-0171 - Notification of receipt [SEC=OFFICIAL]

Dear s47F

FREEDOM OF INFORMATION REQUEST – NOTIFICATION OF RECEIPT

I am writing to notify you that the Therapeutic Goods Administration (Department of Health and Aged Care) has received your request for access to documents under the *Freedom of Information Act 1982* (FOI Act) as follows:

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The timeframe for your request is from 1 January 2023 to 28 February 2025.

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Where there is requirement to undertake consultation with affected third parties, this timeframe is extended by a further 30 days. It may also be extended in certain circumstances, including with your agreement or where the Department applies to the Office of the Australian Information Commissioner for an extension.

Unless you advise otherwise, draft and duplicate documents, Commonwealth employee names and contact details of staff below Senior Executive Service level, internal group email addresses and mobile telephone numbers of all staff will be excluded from the scope of your request under section 22(1)(a)(ii) of the FOI Act.

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In addition, please note that if the decision maker decides that you are liable to pay a charge in relation to your request then this timeframe is extended pending payment of a deposit. You will be notified by the Department if you are liable to pay a charge and/or if third party consultation is required.

If you have any queries, please contact the FOI team on (02) 6289 4630, or via email at TGA.FOI@tga.gov.au.

Kind regards

s22

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Australian Government Department of Health and Aged Care
Address: PO Box 100, Woden ACT, 2606, Australia

E: TGAFOI@tga.gov.au

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Sent: Friday, 28 February 2025 9:32 AM

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Name

s47F

Contact email address**s47F** @ **s47G(1)(a)****Preferred contact number****s47F****s47**

Documents requested

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From date

01/01/2023 - 12:00am

To date

28/02/2025 - 12:00am

Personal information of third parties in documents

Can we remove the personal info of any third parties from the documents

Yes

Can we share your details with any relevant third parties

No

The content of this email and of any files transmitted may contain confidential, proprietary or legally privileged information and is intended solely for the use of the person/s or entity/ies to whom it is addressed. If you have received this email in error you have no permission whatsoever to use, copy, disclose or forward all or any of its contents. Please immediately notify the sender and thereafter delete this email and any attachments.

From: [TGA FOI](#)
To: [s47F](#) @ [s47](#)
Cc: [TGA FOI](#)
Subject: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]
Date: Friday, 21 March 2025 5:01:50 PM
Attachments: [image001.jpg](#)
[FOI 25-0171 - Estimate of Charges.pdf](#)

Dear [s47F](#)

Please find attached correspondence in relation to your Freedom of Information request.

IMPORTANT: Please include reference to FOI 25-0171 in your payment.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

[s22](#)

Freedom of Information

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
Address: PO Box 100, Woden ACT, 2606, Australia

E: TGAFOI@tga.gov.au

T: + 61 2 6289 4630

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Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

s47F
s47

Email: s47F @s47

Dear s47F

FREEDOM OF INFORMATION REQUEST FOI 25-0171
Estimate of Charges

1. I refer to your request dated 28 February 2025 under the *Freedom of Information Act* 1982 (the FOI Act) for access to the following documents:

'Orphan Drug Designation application for Sodium Oxybate for the treatment of narcolepsy, by the sponsor Reach Pharmaceuticals Pty Ltd approved 20 Nov 24, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.

Orphan Drug Designation application for Sebetralstat for the treatment of Hereditary angioedema, by the sponsor JACE Pharma Pty Ltd approved 2 Aug 2024, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.'

The timeframe for your request is from 1 January 2023 to 28 February 2025.

2. Under the *Freedom of Information (Charges) Regulations 2019* (the Regulations) a charge can be imposed in respect of a request for access to documents under the FOI Act. The charge is for the search and retrieval of documents, decision making and provision of access.
3. I am an authorised decision maker under section 23 of the FOI Act and I have decided that you are liable to pay a charge in respect of the processing of your request for access.
4. A search and retrieval of documents relevant to your request has been undertaken and a preliminary estimate of charges has been calculated. It is set out in the table below.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	4 hours @ \$15.00 per hour	\$60.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	13.38 hours @ \$20.00 per hour Less first 5 hours which are free	\$167.57
TOTAL		\$227.57
Deposit required		\$56.89

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$227.57, I have decided you are required to pay a deposit of 25 percent, being \$56.89. Details of how to make a payment are outlined below.
6. Under subsection 29(1) of the FOI Act, I am required to notify you that you have 30 calendar days from receipt of this notice to do one of the following:
 - pay the charge, being the deposit outlined above, and notify the FOI Team via the email below; or
 - notify the TGA that you wish to contend that:
 - the charge has been wrongly assessed, giving reasons; or
 - the charge should be reduced or not imposed (for instance, where payment of the charge would cause you financial hardship or where you believe access to documents is in the general public interest), with reasons; or
 - notify the TGA that you withdraw your request.
7. Please note, should you seek a reduction or waiver of charges on the grounds of financial hardship it would assist the decision maker considering your request if you provide suitable evidence of financial hardship (for example, by providing evidence of receipt of a pension or income support payment; or provide evidence of income, debts or assets). This is consistent with the FOI Guidelines www.oaic.gov.au/freedom-of-information/foi-guidelines/part-4-charges-for-providing-access. Evidence should be provided at the time of seeking waiver or reduction.
8. If you fail to notify the TGA within 30 days about what you propose to do, the FOI Act provides under subsection 29(2) that you are taken to have withdrawn your request.

Timeframes

9. The time limit for processing your request is suspended, in accordance with section 31 of the FOI Act, from the date you receive this notice and resumes on the day you pay the charge or deposit (including any reduced charge or deposit), or the day on which the TGA makes a decision not to impose a charge.
10. Once your FOI request has been processed, the TGA will determine the actual charge you must pay before the documents can be provided to you. The final charge for processing your request may be different from the estimate quoted in this letter. If I decide to grant full access to all the documents within the scope of your request, you must pay the actual charges for the time and disbursements involved in processing your request ascertained in accordance with the table set out above (which may be greater or less than the estimate). However, if you are only granted partial access to the documents, you will only be required to pay whichever amount is the lesser of the estimate quoted in this letter and the actual charges.
11. Please note that the decision maker can make a decision to charge for search and retrieval that the TGA has already undertaken for the purposes of your request in its current form, but it may be possible to reduce the decision making charges that might be incurred by the TGA in the future if you refine the scope of your request, for example, by limiting the date range of documents sought or excluding a particular category of documents.
12. If you agree to pay the charge, you are accepting liability for settlement of the debt upon completion of processing the FOI request. Once your FOI request has been processed, the outstanding amount of the charge becomes a debt to the Commonwealth. The TGA is obliged to pursue recovery of the debt in accordance with the *Public Governance, Performance and Accountability Act 2013*.

Background

13. On 28 February 2025, the TGA received a request from you under the FOI Act. As part of your application, you advised that personal information of third parties is excluded from the scope of your request.

14. On 18 March 2025, the TGA wrote to you to seek clarification regarding the scope of your request, specifically:

'The FOI team has now received documents following the formal search and retrieval process. Within the suite of documents are a large number (in excess of 50) medical papers and journal articles that were provided in support of an application, specifically an orphan drug designation application. I can confirm that these medical papers and journal articles have been listed as references within another document which has been retrieved from the line area for your request.'

'Should you seek access to these documents, the request may be considered too voluminous for the TGA to process. As such, I write to seek your consideration of omitting these medical papers and journal articles from the scope of your request...'

15. On even date, you responded to advise *'...I confirm s47 do not require copies of all the papers submitted in support of the ODDs, provided the reference list is supplied. Thank you.'*

Payment

16. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).

17. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled **'Online payment portal'** to display the payment portal page. From the payment portal page, enter the following information:

- **'Biller Code'**, click on the drop-down arrow to select option **'11 – Freedom of Information (FOI)'**.
- **'Client Identification Number'**, enter **'CO-9001'**.
- **'Reference Number'**, enter your unique FOI identification number followed by your first and last name (e.g. **'FOI-XXXX John Smith'**).
- **'Email Address for Tax Receipt'**, enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
- **'Amount (AUD)'**, enter the amount of the payment being made.
- **'Select your payment option'**, click on the relevant icon to proceed to the next screen.

Please include reference to FOI 25-0171 in your payment.

18. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.

19. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

20. In the event your request relates to documents that include information about a person or their business or professional affairs or about the business, commercial or financial affairs of an organisation or undertaking, pursuant to section 27 and 27A of the FOI Act the TGA will be required to provide that person or organisation the opportunity to make submissions if it appears that they may wish to argue any document is exempt from release.
21. The statutory time limit for processing an FOI request will be extended by 30 days under subsection 15(6) of the FOI Act where a third party is to be consulted.
22. If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Andrew Simpson
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
21 March 2025

From: s47F
To: TGA FOI
Subject: FW: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]
Date: Monday, 24 March 2025 2:25:36 PM
Attachments: [image001.jpg](#)
[image002.jpg](#)
[payment receipt - 5221 7776 671.msg](#)

Dear s22
 Please find attached confirmation of payment of the deposit for FOI 25-0171.
 Thank you
 Kind regards

s47F

s47F
 s47
 s47
 s47
 Mobile s47F
 s47F s47
 s47



Please consider the environment before printing this e-mail.

From: TGA FOI
Sent: Friday, March 21, 2025 5:02 PM
To: s47F
Cc: TGA FOI
Subject: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]

Dear s47F
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IMPORTANT: Please include reference to FOI 25-0171 in your payment.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

s22

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From: no-reply@bpoint.com.au
To: s47F
Subject: payment receipt - 5221 7776 671
Date: Monday, 24 March 2025 2:22:08 PM

BPOINT Payment Receipt

PO Box 100
Woden, ACT, 2606
Phone: 6221 6900
Web: <http://www.tga.gov.au>
Email: accountsrec@health.gov.au

Payment Details

You have paid:

Biller Code: 11
Client Identification Number: CO-9001
Payment Reference: FOI 25-0171 s47F
Email Address for Tax Receipt: s47F@s47
Payment Amount: AUD 56.89
Account Type: MasterCard
Card Number: s47F
Expiry Date: s47F

Authorisation Result - Approved

Payment Date: 24/03/2025 02:21 PM
Time Zone: Sydney, Australia
Receipt Number: 5221 7776 671

From: s47F
To: TGA FOI
Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]
Date: Wednesday, 26 March 2025 4:58:31 PM
Attachments: [image001.jpg](#)
[image002.jpg](#)
[image003.jpg](#)

Thank you very much s22

Kind regards

s47F

s47F

s47

s47

s47

Mobile s47F

s47F @s47

s47



Please consider the environment before printing this e-mail.

From: TGA FOI

Sent: Wednesday, March 26, 2025 4:56 PM

To: s47F

Cc: TGA FOI

Subject: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Dear s47F

Thank you for your email.

We wish to confirm that the TGA received your payment on 24 March 2025 following the estimate of charges process.

As notified in the Estimate of Charges letter sent to you on 21 March 2025, the processing timeframe was suspended under section 31(2)(a) between the time the charges were issued and receipt of a deposit. Accordingly, the processing of your request has recommenced.

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act the timeframe for processing your request has been extended by 30 days to allow the consultation process to be conducted.

The current due date for a decision in relation to your request is **2 May 2025**.

Kind regards

s22

Freedom of Information

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

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Web: www.tga.gov.au

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the author immediately and delete all copies of this transmission.

The Department of Health and Aged Care 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: s47F [REDACTED]@s47 [REDACTED]
Sent: Monday, 24 March 2025 2:25 PM
To: TGA FOI <TGAFOI@health.gov.au>
Subject: FW: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]

Dear s22 [REDACTED]
 Please find attached confirmation of payment of the deposit for FOI 25-0171.
 Thank you
 Kind regards

s47F [REDACTED]

s47F [REDACTED]

s47 [REDACTED]

s47 [REDACTED]

s47 [REDACTED]

Mobile s47F [REDACTED]

s47F [REDACTED]@s47 [REDACTED]

s47 [REDACTED]



Please consider the environment before printing this e-mail.

From: TGA FOI <TGAFOI@health.gov.au>
Sent: Friday, March 21, 2025 5:02 PM
To: s47F [REDACTED]@s47 [REDACTED]
Cc: TGA FOI <TGAFOI@health.gov.au>
Subject: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]

Dear s47F [REDACTED]
 Please find attached correspondence in relation to your Freedom of Information request.

IMPORTANT: Please include reference to FOI 25-0171 in your payment.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

s22 [REDACTED]

Freedom of Information

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

Address: PO Box 100, Woden ACT, 2606, Australia

E: TGAFOI@tga.gov.au

T: + 61 2 6289 4630

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From: TGA FOI
To: s47F
Cc: TGA FOI
Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]
Date: Thursday, 17 April 2025 2:10:17 PM
Attachments: [image002.png](#)
[image003.jpg](#)
[image004.jpg](#)
[image005.jpg](#)

Thank you so much s47F have a lovely easter.

Kind regards

s22

Freedom of Information

Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care
 T: 02 6289 4630 | E: TGAFOI@health.gov.au
 PO Box 100, Woden ACT 2606, Australia
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From: s47F
Sent: Thursday, 17 April 2025 1:44 PM
To: TGA FOI
Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]
 Dear s22
 I confirm s47 accept the proposed extension.
 Thank you
 Kind regards
 s47F

s47F
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 Mobile s47F
 s47F @s47
 s47



Please consider the environment before printing this e-mail.

From: TGA FOI <TGAFOI@health.gov.au>
Sent: Thursday, April 17, 2025 1:37 PM
To: s47F @s47
Cc: TGA FOI <TGAFOI@health.gov.au>
Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Good afternoon **s47F**

I refer to previous correspondence regarding your FOI request, and I can advise that the TGA is continuing to process your FOI request.

As an update, the TGA is currently preparing to consult with relevant third parties. However, due to the current ACT school holiday period and the upcoming public holidays associated with Easter and ANZAC Day, resulting in annual leave for key staff members that will be involved with providing input to your request, it has become apparent that the TGA may not be able to meet the current deadline for processing your request and accordingly, we ask that you consider granting a short extension of time under s 15AA of the FOI Act, of **15 days** for a decision to be provided in this matter. A decision will be due on or before **17 May 2025**.

I do not anticipate further delays, however we would be very grateful for your understanding and acceptance of our request for a short extension.

Due to the imminent deadline for your request, we would be grateful for your response by **COB Tuesday 22 April 2025**.

Thank you for your patience in this matter and for your further consideration of our request.

Please do not hesitate to contact the FOI team if you have any questions.

Kind regards

s22

Freedom of Information

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

T: 02 6289 4630 | E: TGAFOI@health.gov.au

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From: **s47F** @**s47**

Sent: Wednesday, 26 March 2025 4:58 PM

To: TGA FOI <TGAFOI@health.gov.au>

Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Thank you very much **s22**

Kind regards

s47F

s47F

s47

s47

s47

Mobile **s47F**

s47F @**s47**

s47



Please consider the environment before printing this e-mail.

From: TGA FOI <TGAFOI@health.gov.au>
Sent: Wednesday, March 26, 2025 4:56 PM
To: s47F [REDACTED] @s47 [REDACTED]
Cc: TGA FOI <TGAFOI@health.gov.au>
Subject: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Dear s47F [REDACTED]

Thank you for your email.

We wish to confirm that the TGA received your payment on 24 March 2025 following the estimate of charges process.

As notified in the Estimate of Charges letter sent to you on 21 March 2025, the processing timeframe was suspended under section 31(2)(a) between the time the charges were issued and receipt of a deposit. Accordingly, the processing of your request has recommenced.

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act the timeframe for processing your request has been extended by 30 days to allow the consultation process to be conducted.

The current due date for a decision in relation to your request is **2 May 2025**.

Kind regards

s22

Freedom of Information

Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care
 T: 02 6289 4630 | E: TGAFOI@health.gov.au
 PO Box 100, Woden ACT 2606, Australia
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From: s47F [REDACTED] @s47 [REDACTED]
Sent: Monday, 24 March 2025 2:25 PM
To: TGA FOI <TGAFOI@health.gov.au>
Subject: FW: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]

Dear s22

Please find attached confirmation of payment of the deposit for FOI 25-0171.

Thank you

Kind regards

s47F [REDACTED]

s47F [REDACTED]
 s47 [REDACTED]
 s47 [REDACTED]
 s47 [REDACTED]
 Mobile s47F [REDACTED]
 s47F [REDACTED] @s47 [REDACTED]
 s47 [REDACTED]



Please consider the environment before printing this e-mail.

From: TGA FOI <TGAFOI@health.gov.au>

Sent: Friday, March 21, 2025 5:02 PM

To: s47F [REDACTED]@s47 [REDACTED]

Cc: TGA FOI <TGAFOI@health.gov.au>

Subject: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]

Dear s47F [REDACTED]

Please find attached correspondence in relation to your Freedom of Information request.

IMPORTANT: Please include reference to FOI 25-0171 in your payment.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

s22 [REDACTED]

Freedom of Information

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

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E: TGAFOI@tga.gov.au

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From: TGA FOI
To: s47F
Cc: TGA FOI
Subject: RE: FOI 0171 - Request for further extension [SEC=OFFICIAL]
Date: Wednesday, 7 May 2025 11:47:56 AM
Attachments: [image001.png](#)
[image002.jpg](#)
[image003.jpg](#)
[image004.jpg](#)

Thank you very much s47F for your patience and understanding.

We will be in contact with you shortly.

Kind regards

s22

Freedom of Information

Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care
 T: 02 6289 4630 | E: TGAFOI@health.gov.au
 PO Box 100, Woden ACT 2606, Australia
 Web: www.tga.gov.au

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From: s47F
Sent: Wednesday, 7 May 2025 11:41 AM
To: TGA FOI
Subject: RE: FOI 0171 - Request for further extension [SEC=OFFICIAL]

Dear s22

s47F accepts the extension until the 1 June 2025.

Thank you

Kind regards

s47F

s47F
 s47
 s47
 s47
 Mobile s47F
 s47F @s47
 s47

From: TGA FOI <TGAFOI@health.gov.au>
Sent: Wednesday, 7 May 2025 11:22 AM
To: s47F @s47
Cc: TGA FOI <TGAFOI@health.gov.au>
Subject: RE: FOI 0171 - Request for further extension [SEC=OFFICIAL]
 Good morning s47F

I refer to previous correspondence regarding your FOI request, and I can advise that the TGA is continuing to process your FOI request.

As an update, the TGA is currently consulting with relevant third parties. One of those parties has sought additional time to provide their response as it is necessary for them to communicate with their counterparts who are not based in Australia. It would be appreciated if you would consider a further extension of time under s 15AA of the FOI Act, of **15 days** for a decision to be provided in this matter. This will allow the decision maker to consider all submissions in forming their submission. A decision will be due on or before **1 June 2025**.

Thank you for your patience and I would be very grateful for your acceptance of our request for a short extension.

Due to the imminent deadline for your request, we would be grateful for your response by **COB tomorrow, Thursday 8 May 2025**.

Please do not hesitate to contact the FOI team if you have any questions.

Kind regards

s22

Freedom of Information

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 Australian Government Department of Health and Aged Care
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 PO Box 100, Woden ACT 2606, Australia
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From: TGA FOI <TGAFOI@health.gov.au>

Sent: Thursday, 17 April 2025 2:10 PM

To: **s47F** **@s47**

Cc: TGA FOI <TGAFOI@health.gov.au>

Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Thank you so much **s47F** have a lovely easter.

Kind regards

s22

Freedom of Information

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 Australian Government Department of Health and Aged Care
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From: s47F s47
Sent: Thursday, 17 April 2025 1:44 PM
To: TGA FOI <TGAFOI@health.gov.au>
Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Dear s22
 I confirm s47 accept the proposed extension.
 Thank you
 Kind regards
 s47F

s47F
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 Mobile s47F
 s47F @s47
 s47



Please consider the environment before printing this e-mail.

From: TGA FOI <TGAFOI@health.gov.au>
Sent: Thursday, April 17, 2025 1:37 PM
To: s47F @s47
Cc: TGA FOI <TGAFOI@health.gov.au>
Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Good afternoon s47F

I refer to previous correspondence regarding your FOI request, and I can advise that the TGA is continuing to process your FOI request.

As an update, the TGA is currently preparing to consult with relevant third parties. However, due to the current ACT school holiday period and the upcoming public holidays associated with Easter and ANZAC Day, resulting in annual leave for key staff members that will be involved with providing input to your request, it has become apparent that the TGA may not be able to meet the current deadline for processing your request and accordingly, we ask that you consider granting a short extension of time under s 15AA of the FOI Act, of **15 days** for a decision to be provided in this matter. A decision will be due on or before **17 May 2025**.

I do not anticipate further delays, however we would be very grateful for your understanding and acceptance of our request for a short extension.

Due to the imminent deadline for your request, we would be grateful for your response by **COB Tuesday 22 April 2025**.

Thank you for your patience in this matter and for your further consideration of our request.

Please do not hesitate to contact the FOI team if you have any questions.

Kind regards

s22

Freedom of Information

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

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From: s47F @s47

Sent: Wednesday, 26 March 2025 4:58 PM

To: TGA FOI <TGAFOI@health.gov.au>

Subject: RE: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Thank you very much s22

Kind regards

s47F

s47F

s47

s47

s47

Mobile s47F

s47F @s47

s47



Please consider the environment before printing this e-mail.

From: TGA FOI <TGAFOI@health.gov.au>

Sent: Wednesday, March 26, 2025 4:56 PM

To: s47F @s47

Cc: TGA FOI <TGAFOI@health.gov.au>

Subject: FOI 0171 - Timeframes following payment [SEC=OFFICIAL]

Dear s47F

Thank you for your email.

We wish to confirm that the TGA received your payment on 24 March 2025 following the estimate of charges process.

As notified in the Estimate of Charges letter sent to you on 21 March 2025, the processing timeframe was suspended under section 31(2)(a) between the time the charges were issued and receipt of a deposit. Accordingly, the processing of your request has recommenced.

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act the timeframe for processing your request has been extended by 30 days to allow the consultation process to be conducted.

The current due date for a decision in relation to your request is **2 May 2025**.

Kind regards

s22**Freedom of Information**

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 Australian Government Department of Health and Aged Care
 T: 02 6289 4630 | E: TGAFOI@health.gov.au
 PO Box 100, Woden ACT 2606, Australia
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From: **s47F** @**s47**
Sent: Monday, 24 March 2025 2:25 PM
To: TGA FOI <TGAFOI@health.gov.au>
Subject: FW: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]
 Dear **s22**
 Please find attached confirmation of payment of the deposit for FOI 25-0171.
 Thank you
 Kind regards
s47F

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 Mobile **s47F**
s47F @**s47**
s47



Please consider the environment before printing this e-mail.

From: TGA FOI <TGAFOI@health.gov.au>
Sent: Friday, March 21, 2025 5:02 PM
To: **s47F** **s47**
Cc: TGA FOI <TGAFOI@health.gov.au>
Subject: FOI 0171 - Notice of Estimate of Charges [SEC=OFFICIAL]
 Dear **s47F**

Please find attached correspondence in relation to your Freedom of Information request.

IMPORTANT: Please include reference to FOI 25-0171 in your payment.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

s22**Freedom of Information**

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
Address: PO Box 100, Woden ACT, 2606, Australia

E: TGAFOI@tga.gov.au

T: + 61 2 6289 4630

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From: [TGA FOI](#)
To: s47F [REDACTED] @s47 [REDACTED]
Cc: [TGA FOI](#)
Subject: FOI 25-0171 - Notice of Decision [SEC=OFFICIAL]
Date: Tuesday, 3 June 2025 4:37:18 PM
Attachments: [image001.jpg](#)
[FOI 25-0171 - Notice of Decision.pdf](#)
[Document 2 AR.pdf](#)
[Document 3 AR.pdf](#)
[Document 4 AR.pdf](#)
[Document 5 AR.pdf](#)
[Document 8.PDF](#)
[Document 9 AR.pdf](#)
[Document 13 AR.pdf](#)

Dear s47F [REDACTED]

Please find attached correspondence in relation to your Freedom of Information request.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

s22 [REDACTED]

Freedom of Information

Therapeutic Goods Administration

Australian Government Department of Health, Disability and Ageing

Address: PO Box 100, Woden ACT, 2606, Australia

E: TGAFOI@tga.gov.au

T: + 61 2 6289 4630

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Australian Government

Department of Health, Disability and Ageing Therapeutic Goods Administration

s47F
s47

Email: [REDACTED]@s47

Dear s47F

FREEDOM OF INFORMATION REQUEST FOI 25-0171 Notice of Decision

1. I refer to your request dated 28 February 2025 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'Orphan Drug Designation application for Sodium Oxybate for the treatment of narcolepsy, by the sponsor Reach Pharmaceuticals Pty Ltd approved 20 Nov 24, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.'

Orphan Drug Designation application for Sebetralstat for the treatment of Hereditary angioedema, by the sponsor JACE Pharma Pty Ltd approved 2 Aug 2024, and any correspondence related to this application (prior to designation submission and following designation submission) to and from TGA and Sponsor.'

The timeframe for your request is from 1 January 2023 to 28 February 2025.

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Scope of the FOI request

3. The TGA has identified 13 documents falling within the scope of your request.

Background

4. On 28 February 2025, the TGA received a request from you under the FOI Act. As part of your application, you advised that personal information of third parties is excluded from the scope of your request.

5. On 18 March 2025, the TGA sought clarification from you regarding the scope of your request following the search and retrieval processes that was conducted:

'...The FOI team has now received documents following the formal search and retrieval process. Within the suite of documents are a large number (in excess of 50) medical papers and journal articles that were provided in support of an application, specifically an orphan drug designation application. I can confirm that these medical papers and journal articles have been listed as references within another document which has been retrieved from the line area for your request.'

Should you seek access to these documents, the request may be considered too voluminous for the TGA to process. As such, I write to seek your consideration of omitting these medical papers and journal articles from the scope of your request....'

6. On the same day, you responded to confirm that s47 *do not require copies of all the papers submitted in support of the ODDs, provided the reference.*
7. On 21 March 2025, you were advised that the cost of processing your request amounted to \$227.57 and you were asked to pay a deposit of \$56.89. You were also advised at this time of the need to conduct third party consultation in relation to your request.
8. On 24 March 2025, the TGA received a deposit in the amount of \$56.89 for the processing of your request and you were notified of the current due date for a decision in relation to your request following the estimate of charges process. Third party consultation was subsequently initiated.
9. On 17 April 2025, you agreed to a 15-day extension under section 15AA of the FOI Act for the processing of your FOI request.
10. On 7 May 2025, you agreed to a further 15-day extension under section 15AA of the FOI Act for the processing of your FOI request.

Material Considered in Decision-Making

11. In coming to my decision I had regard to the following:
 - the correspondence between the TGA and yourself;
 - the documents falling within the scope of the FOI request;
 - the provisions of the FOI Act, in particular sections 22, 47 and 47G;
 - the guidelines issued by the Office of the Australian Information Commissioner (OAIC) under section 93A of the FOI Act; and
 - consultation with third parties whose documents are involved.

Decision

12. My decision in relation to the documents falling within the scope of your FOI request is to:
 - release one document in full;
 - release 6 documents in part; and
 - not release 6 documents.
13. My decision not to provide you with full access to the documents is based on the application of sections 22, 47 and 47G of the FOI Act.
14. The preliminary estimate of charges associated with processing this FOI request was \$227.57. This amount includes the first five hours of decision making at no cost. In accordance with the *Freedom of Information (Charges) Regulations 2019* (the Charges Regulations) I have calculated the actual charges that can be imposed for processing your request. In this case, the actual charges that can be imposed are \$60.00. However, given the number of documents and the minor difference between the deposit paid and actual charges, I have decided not to impose the actual charges.
15. Accordingly, the applicable documents will be provided to you with this decision.

Reasons for Decision

Relevant Documents

16. The TGA has identified 13 documents relevant to your request. A schedule listing the documents is at **Attachment A**.

17. The schedule indicates for each document my decision to release in full, release in part or exempt in full and refers to the exemption provisions which are claimed to apply to each document.
18. The reasons for the application of these exemption provisions to the documents in issue are set out in detail below. A copy of the relevant provisions of the FOI Act is at **Attachment B**.

Subsection 22(1): Documents containing information that is irrelevant to the FOI request

19. The effect of subsection 22(1) of the FOI Act is that where the granting of access to a document would disclose information that is not within the scope of the request and it is possible to provide a copy with information deleted, the agency can do so unless it is evident that the applicant does not wish to be provided access to such a copy. A copy of subsection 22(1) is at **Attachment B**.
20. The relevant documents contain information that does not fall within the scope of your FOI request. Specifically, parts of Documents 2-5, 9 and 13 contain:
 - a. personal information such as individual's names, phone numbers and email addresses, which you confirmed are not part of your request.
 - b. personal information such as TGA staff names, numbers, internal email addresses which you were advised would be removed unless you advised otherwise.
21. I consider that to provide you with full access to the documents would disclose the above information that does not fall within the scope of your FOI request. Accordingly, I have decided that the irrelevant information will be deleted under section 22(1) of the FOI Act and a copy of the documents, with the irrelevant information deleted, will be provided to you.

Section 47: Documents are exempt documents if they contain a trade secret

22. Under s47 of the FOI Act, a document is an exempt document if it contains a trade secret (s47(1)(a)) or contains information that has commercial value that could reasonably be expected to be destroyed or diminished if it were disclosed (s47(1)(b)). I consider any information that has a commercial value would also include any information that is a trade secret. Therefore, I have only considered whether the information in question has a commercial value. A copy of s47(1)(b) is at **Attachment B**.
23. Paragraph 5.205 of the FOI Guidelines states that the following factors may assist in deciding in a particular case whether information has a commercial value:
 - whether the information is known only to the agency or person for whom it has value or, if it is known to others, to what extent that detracts from its intrinsic commercial value
 - whether the information confers a competitive advantage on the agency or person to whom it relates – for example, if it lowers the cost of production or allows access to markets not available to competitors;
 - whether a genuine 'arm's-length' buyer would be prepared to pay to obtain that information;
 - whether the information is still current or out of date (out of date information may no longer have any value); and
 - whether disclosing the information would reduce the value of a business operation or commercial activity – reflected, perhaps, in a lower share price.

24. Having regard to the submissions of the third parties and considering the FOI Guidelines, I am satisfied that the information contained in Documents 1, 6-7 and 10-12 is commercially valuable information, the value of which would be diminished or destroyed if disclosed.
25. The documents in question set out the submissions Reach Pharmaceuticals and Jace Pharma made in obtaining orphan drug designation for their respective products - Sodium Oxybate and Sebetralstat.
26. Specifically, the documents contain information relating to:
 - Proprietary product formulation;
 - Comparisons against other registered therapeutic goods;
 - Stages of development; and
 - Research insights and market strategy.
27. I am satisfied that a competitor to both Reach Pharmaceuticals Pty Ltd and Jace Pharma Pty Ltd would be prepared to pay to obtain this information to assist in submitting its own regulatory application for orphan drug designation, and that would have a detrimental impact on their market position in the industry and would have financial and commercial impacts for their businesses.
28. I am further satisfied that disclosure of these documents would unfairly provide the requester a shortcut by way of time, effort and expense by leveraging proprietary information, which holds significant strategic and commercial value.
29. In this regard, I am satisfied that the information is of a commercial value to Reach Pharmaceuticals and Jace Pharma, the value of which would be diminished or destroyed if released, and accordingly I am satisfied that such information is exempt under section 47 of the Act.
30. Accordingly, parts of the documents (as identified in the schedule at **Attachment A**) are exempt under section 47(1)(b) of the FOI Act and therefore have been deleted from the documents.

Paragraph 47G(1)(a) – unreasonable adverse effect on business affairs

31. A document is conditionally exempt under paragraph 47G(1)(a) of the FOI Act where disclosure of information concerning the business affairs of an organisation would, or could reasonably be expected to, unreasonably affect the person adversely in respect of their business affairs. A copy of paragraph 47G(1)(a) is at **Attachment B**.
32. Document 13 contains the identity of the regulatory consulting firm who is acting on behalf of the sponsor of the relevant medicine. I note that the relevant sponsor has objected to the release of this information.
33. I consider that the disclosure of the name of the regulatory consulting firm may have an unreasonable adverse effect on its business, as it would associate the firm with a particular matter and/or sponsor that may impact on its existing and future commercial operations. I note that the regulatory agent is not publicly known to be associated with the sponsor. Therefore, I am satisfied that the release of information in this document is also conditionally exempt under paragraph 47G(1)(a) of the FOI Act.
34. For the information to be considered exempt under paragraph 47G(1)(a), I would need to be satisfied that the release of the information would, or could reasonably be expected to,

unreasonably affect that business adversely in respect of their lawful business or professional affairs.

35. In determining whether any adverse effect is 'unreasonable', it is necessary to undertake a balancing of relevant interests.
36. In the present case, I am satisfied that it would be unreasonable to disclose the regulatory agent's information, as disclosure would have an adverse effect on the business of the regulatory agent. I am also satisfied that there is no overarching public interest of the kind referred to in the FOI Guidelines that would make such disclosure justified and reasonable.
37. The regulatory agent provides confidential and impartial consultancy advice to businesses and releasing their name in connection with a particular business could affect their viability. The information contained in these documents is not disclosed to the general public or its competitors, rather, it has only been submitted (in confidence) for the purpose of seeking TGA approval.
38. Further, I am satisfied that information contained within the document is conditionally exempt under paragraph 47G(1)(a) as disclosure would, or could reasonably be expected to, unreasonably affect the firm in respect of its lawful business and commercial affairs. However, I am required under subsection 11A(5) of the FOI Act to give access to the information unless it would, at this time, on balance, be contrary to the public interest.
39. In relation to the factors favouring giving access to the information, I have considered the following:
 - the general public interest in obtaining access to government-held information; and
 - the objects of the FOI Act which encourages access to information held by government agencies, subject only to certain exemptions.
40. In relation to the factors against giving access to the information, I have considered the following:
 - the public interest in preserving confidentiality having regard to the sensitivity of the information and the circumstance in which the information was communicated to the TGA;
 - the likelihood that release of the document would or could have an unreasonable adverse effect on the business affairs of the relevant consulting firm; and
 - the public interest in ensuring the integrity and viability of the regulatory process of the TGA, specifically regarding the registration of a therapeutic good.
41. On balance, I consider that giving access to the information at this time would be contrary to the public interest.
42. For the reasons set out above, I have decided not to disclose some of the information contained within Document 13 (as identified in the schedule at **Attachment A**) and the rest of the document may be disclosed to you.

Release of Documents

43. As there are no outstanding charges for the processing of your FOI request, the documents that are not exempt from release are now being provided to you with this decision.

Review and Complaint Rights

44. If you are not satisfied with this decision, you have 30 calendar days to either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: [Apply for an Information Commissioner Review | Office of the Australian Information Commissioner](#).

If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

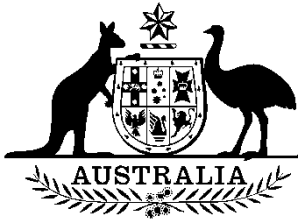
Andrew Simpson
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
3 June 2025

Schedule of Relevant Documents

Doc. No.	Author	Addressee	Date	Description	Pages	Decision	Relevant Sections of the FOI Act
1	Reach Pharmaceuticals Pty Ltd	TGA	13/11/2024	PM-2024-05368-1-1 - ODD Application TGA sodium oxybate resubmission Nov 2024	20	Exempt from release	s47
2	Reach Pharmaceuticals Pty Ltd	TGA	23/01/2025	RE: Orphan drug designation application outcome letter - PM-2024-05368-1-1 - sodium oxybate	1	Release in part	s22
3	TGA	Reach Pharmaceuticals Pty Ltd	20/11/2024	Orphan drug designation application outcome letter - PM-2024-05368-1-1 - sodium oxybate	3	Release in part	s22
4	Reach Pharmaceuticals Pty Ltd	TGA	15/11/2024	Response to Request for information - Orphan drug designation - PM-2024-05368-1-1 - sodium oxybate	1	Release in part	s22

Doc. No.	Author	Addressee	Date	Description	Pages	Decision	Relevant Sections of the FOI Act
5	TGA	Reach Pharmaceuticals Pty Ltd	15/11/2024	Request for information - Orphan drug designation - PM-2024-05368-1-1 - sodium oxybate [SEC=OFFICIAL] - Email 15-11-2024 13:42:37 (0)	1	Release in part	s22
6	JACE Pharma Pty Ltd	TGA	31/07/2024	Australia ODD Application_V1.0	22	Exempt from release	s47
7	Third party	TGA	31/07/2024	Cover letter - ODD	12	Exempt from release	s47
8	JACE Pharma Pty Ltd	TGA	31/07/2024	designation-checklist-sponsor-seeking-orphan-drug-designation	2	Release in full	-
9	JACE Pharma Pty Ltd	TGA	31/07/2024	220621 Commission Implementing Decision C_2022_4421_1_EN_ACT_part1_v2	3	Release in part	s22
10	JACE Pharma Pty Ltd	TGA	31/07/2024	KVD900-201_Study Report Synopsis_16Nov2021	22	Exempt from release	s47

Doc. No.	Author	Addressee	Date	Description	Pages	Decision	Relevant Sections of the FOI Act
11	JACE Pharma Pty Ltd	TGA	31/07/2024	kvd900-301-synopsis	22	Exempt from release	s47
12	JACE Pharma Pty Ltd	TGA	31/07/2024	kvd900-302-synopsis	19	Exempt from release	s47
13	TGA	Third party	02/08/2024	(AET email to Sponsor) - PM-2024-03443-1-2 - sebetralstat (EKTERLY) - Orphan Outcome letter	3	Release in part	s22 s47G



Freedom of Information Act 1982

11A Access to documents on request

- (5) The agency or Minister must give the person access to the document if it is conditionally exempt at a particular time unless (in the circumstances) access to the document at that time would, on balance, be contrary to the public interest.

Note 1: Division 3 of Part IV provides for when a document is conditionally exempt.

Note 2: A conditionally exempt document is an exempt document if access to the document would, on balance, be contrary to the public interest (see section 31B (exempt documents for the purposes of Part IV)).

Note 3: Section 11B deals with when it is contrary to the public interest to give a person access to the document.

17 Requests involving use of computers etc.

- (1) Where:
- (a) a request (including a request in relation to which a practical refusal reason exists) is made in accordance with the requirements of subsection 15(2) to an agency;
 - (b) it appears from the request that the desire of the applicant is for information that is not available in discrete form in written documents of the agency; and
 - (ba) it does not appear from the request that the applicant wishes to be provided with a computer tape or computer disk on which the information is recorded; and
 - (c) the agency could produce a written document containing the information in discrete form by:
 - (i) the use of a computer or other equipment that is ordinarily available to the agency for retrieving or collating stored information; or
 - (ii) the making of a transcript from a sound recording held in the agency;
- the agency shall deal with the request as if it were a request for access to a written document so produced and containing that information and, for that purpose, this Act applies as if the agency had such a document in its possession.
- (2) An agency is not required to comply with subsection (1) if compliance would substantially and unreasonably divert the resources of the agency from its other operations.

22 Deletion of exempt matter or irrelevant material

- (1) Where:
- (a) an agency or Minister decides:
 - (i) not to grant a request for access to a document on the ground that it is an exempt document; or

- (ii) that to grant a request for access to a document would disclose information that would reasonably be regarded as irrelevant to that request; and
 - (b) it is possible for the agency or Minister to make a copy of the document with such deletions that the copy:
 - (i) would not be an exempt document; and
 - (ii) would not disclose such information; and
 - (c) it is reasonably practicable for the agency or Minister, having regard to the nature and extent of the work involved in deciding on and making those deletions and the resources available for that work, to make such a copy;
- the agency or Minister shall, unless it is apparent from the request or as a result of consultation by the agency or Minister with the applicant, that the applicant would not wish to have access to such a copy, make, and grant access to, such a copy.
- (2) Where access is granted to a copy of a document in accordance with subsection (1):
- (a) the applicant must be informed:
 - (i) that it is such a copy; and
 - (ii) of the ground for the deletions; and
 - (iii) if any matter deleted is exempt matter because of a provision of this Act—that the matter deleted is exempt matter because of that provision; and
 - (b) section 26 does not apply to the decision that the applicant is not entitled to access to the whole of the document unless the applicant requests the agency or Minister to furnish to him or her a notice in writing in accordance with that section.

27 Consultation—business documents

Scope

- (1) This section applies if:
- (a) a request is made to an agency or Minister for access to a document containing information (***business information***) covered by subsection (2) in respect of a person, organisation or undertaking; and
 - (b) it appears to the agency or Minister that the person, organisation or proprietor of the undertaking (the ***person or organisation concerned***) might reasonably wish to make a contention (the ***exemption contention***) that:
 - (i) the document is exempt under section 47 (trade secrets etc.); or
 - (ii) the document is conditionally exempt under section 47G (business information) and access to the document would, on balance, be contrary to the public interest for the purposes of subsection 11A(5).
- Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).
- (2) This subsection covers the following information:
- (a) in relation to a person—information about the person’s business or professional affairs;
 - (b) in relation to an organisation or undertaking—information about the business, commercial or financial affairs of the organisation or undertaking.
- (3) In determining, for the purposes of paragraph (1)(b), whether the person or organisation concerned might reasonably wish to make an exemption contention

because of business information in a document, the agency or Minister must have regard to the following matters:

- (a) the extent to which the information is well known;
- (b) whether the person, organisation or undertaking is known to be associated with the matters dealt with in the information;
- (c) the availability of the information from publicly accessible sources;
- (d) any other matters that the agency or Minister considers relevant.

Opportunity to make submissions

- (4) The agency or Minister must not decide to give access to the document unless:
 - (a) the person or organisation concerned is given a reasonable opportunity to make submissions in support of the exemption contention; and
 - (b) the agency or the Minister has regard to any submissions so made.
- (5) However, subsection (4) only applies if it is reasonably practicable for the agency or Minister to give the person or organisation concerned a reasonable opportunity to make submissions in support of the exemption contention, having regard to all the circumstances (including the application of subsections 15(5) and (6) (time limits for processing requests)).

Notice of decision to give access

- (6) If the agency or Minister decides to give access to the document, the agency or Minister must give written notice of the decision to both of the following:
 - (a) the person or organisation concerned;
 - (b) the applicant.

Access not to be given until review or appeal opportunities have run out

- (7) However, the agency or Minister must not give the applicant access to the document unless, after all the opportunities of the person or organisation concerned for review or appeal in relation to the decision to give access to the document have run out, the decision to give access still stands, or is confirmed.
 - Note 1: The decision to give access to the document is subject to internal review (see Part VI), review by the Information Commissioner (see Part VII) and review by the Tribunal (see Part VIIA).
 - Note 2: For when all opportunities for review or appeal in relation to the decision to give access to the document have **run out**, see subsection 4(1).

Notice and stay of decision not to apply unless submission made in support of exemption contention

- (8) Subsections (6) and (7) do not apply unless the person or organisation concerned makes a submission in support of the exemption contention as allowed under paragraph (4)(a).

Edited copies and business information

- (9) This section applies:
 - (a) in relation to an edited copy of a document—in the same way as it applies to the document; and
 - (b) in relation to a document containing business information—to the extent to which the document contains such information.

27A Consultation—documents affecting personal privacy

Scope

- (1) This section applies if:
- (a) a request is made to an agency or Minister for access to a document containing personal information about a person (including a person who has died); and
 - (b) it appears to the agency or Minister that the person or the person's legal personal representative (the **person concerned**) might reasonably wish to make a contention (the **exemption contention**) that:
 - (i) the document is conditionally exempt under section 47F; and
 - (ii) access to the document would, on balance, be contrary to the public interest for the purposes of subsection 11A(5).

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).

- (2) In determining, for the purposes of paragraph (1)(b), whether the person concerned might reasonably wish to make an exemption contention because of personal information in a document, the agency or Minister must have regard to the following matters:
- (a) the extent to which the information is well known;
 - (b) whether the person to whom the information relates is known to be (or to have been) associated with the matters dealt with in the information;
 - (c) the availability of the information from publicly accessible sources;
 - (d) any other matters that the agency or Minister considers relevant.

Opportunity to make submissions

- (3) The agency or Minister must not decide to give the applicant access to the document unless:
- (a) the person concerned is given a reasonable opportunity to make submissions in support of the exemption contention; and
 - (b) the agency or the Minister has regard to any submissions so made.
- (4) However, subsection (3) only applies if it is reasonably practicable for the agency or Minister to give the person concerned a reasonable opportunity to make submissions in support of the exemption contention, having regard to all the circumstances (including the application of subsections 15(5) and (6) (time limits for processing requests)).

Decision to give access

- (5) If the agency or Minister decides to give access to the document, the agency or Minister must give written notice of the decision to both of the following:
- (a) the person concerned;
 - (b) the applicant.

Access not to be given until review or appeal opportunities have run out

- (6) However, the agency or Minister must not give the applicant access to the document unless, after all the opportunities of the person concerned for review or appeal in relation to the decision to give access to the document have run out, the decision to give access still stands, or is confirmed.

Note 1: The decision to give access to the document is subject to internal review (see Part VI), review by the Information Commissioner (see Part VII) and review by the Tribunal (see Part VIIA).

Note 2: For when all opportunities for review or appeal in relation to the decision to give access to the document have **run out**, see subsection 4(1).

Notice and stay of decision not to apply unless submission made in support of exemption contention

- (7) Subsections (5) and (6) do not apply unless the person concerned makes a submission in support of the exemption contention as allowed under paragraph (3)(a).

Edited copies and personal information

- (8) This section applies:
- (a) in relation to an edited copy of a document—in the same way as it applies to the document; and
 - (b) in relation to a document containing personal information—to the extent to which the document contains such information.

33 Documents affecting national security, defence or international relations

A document is an exempt document if disclosure of the document under this Act:

- (a) would, or could reasonably be expected to, cause damage to:
 - (i) the security of the Commonwealth;
 - (ii) the defence of the Commonwealth; or
 - (iii) the international relations of the Commonwealth; or
- (b) would divulge any information or matter communicated in confidence by or on behalf of a foreign government, an authority of a foreign government or an international organization to the Government of the Commonwealth, to an authority of the Commonwealth or to a person receiving the communication on behalf of the Commonwealth or of an authority of the Commonwealth.

37 Documents affecting enforcement of law and protection of public safety

- (1) A document is an exempt document if its disclosure under this Act would, or could reasonably be expected to:
- (a) prejudice the conduct of an investigation of a breach, or possible breach, of the law, or a failure, or possible failure, to comply with a law relating to taxation or prejudice the enforcement or proper administration of the law in a particular instance;
 - (b) disclose, or enable a person to ascertain, the existence or identity of a confidential source of information, or the non-existence of a confidential source of information, in relation to the enforcement or administration of the law; or
 - (c) endanger the life or physical safety of any person.
- (2) A document is an exempt document if its disclosure under this Act would, or could reasonably be expected to:
- (a) prejudice the fair trial of a person or the impartial adjudication of a particular case;

- (b) disclose lawful methods or procedures for preventing, detecting, investigating, or dealing with matters arising out of, breaches or evasions of the law the disclosure of which would, or would be reasonably likely to, prejudice the effectiveness of those methods or procedures; or
 - (c) prejudice the maintenance or enforcement of lawful methods for the protection of public safety.
- (2A) For the purposes of paragraph (1)(b), a person is taken to be a confidential source of information in relation to the enforcement or administration of the law if the person is receiving, or has received, protection under a program conducted under the auspices of the Australian Federal Police, or the police force of a State or Territory, for the protection of:
 - (a) witnesses; or
 - (b) people who, because of their relationship to, or association with, a witness need, or may need, such protection; or
 - (c) any other people who, for any other reason, need or may need, such protection.
- (3) In this section, **law** means law of the Commonwealth or of a State or Territory.

42 Documents subject to legal professional privilege

- (1) A document is an exempt document if it is of such a nature that it would be privileged from production in legal proceedings on the ground of legal professional privilege.
- (2) A document is not an exempt document because of subsection (1) if the person entitled to claim legal professional privilege in relation to the production of the document in legal proceedings waives that claim.
- (3) A document is not an exempt document under subsection (1) by reason only that:
 - (a) the document contains information that would (apart from this subsection) cause the document to be exempt under subsection (1); and
 - (b) the information is operational information of an agency.

45 Documents containing material obtained in confidence

- (1) A document is an exempt document if its disclosure under this Act would found an action, by a person (other than an agency, the Commonwealth or Norfolk Island), for breach of confidence.
- (2) Subsection (1) does not apply to a document to which subsection 47C(1) (deliberative processes) applies (or would apply, but for subsection 47C(2) or (3)), that is prepared by a Minister, a member of the staff of a Minister, or an officer or employee of an agency, in the course of his or her duties, or by a prescribed authority or Norfolk Island authority in the performance of its functions, for purposes relating to the affairs of an agency or a Department of State unless the disclosure of the document would constitute a breach of confidence owed to a person or body other than:
 - (a) a person in the capacity of Minister, member of the staff of a Minister or officer of an agency; or
 - (b) an agency, the Commonwealth or Norfolk Island.

47 Documents disclosing trade secrets or commercially valuable information

- (1) A document is an exempt document if its disclosure under this Act would disclose:
 - (a) trade secrets; or
 - (b) any other information having a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.
- (2) Subsection (1) does not have effect in relation to a request by a person for access to a document:
 - (a) by reason only of the inclusion in the document of information concerning that person in respect of his or her business or professional affairs; or
 - (b) by reason only of the inclusion in the document of information concerning the business, commercial or financial affairs of an undertaking where the person making the request is the proprietor of the undertaking or a person acting on behalf of the proprietor; or
 - (c) by reason only of the inclusion in the document of information concerning the business, commercial or financial affairs of an organisation where the person making the request is the organisation or a person acting on behalf of the organisation.
- (3) A reference in this section to an undertaking includes a reference to an undertaking that is carried on by, or by an authority of, the Commonwealth, Norfolk Island or a State or by a local government authority.

47B Commonwealth-State relations etc

A document is conditionally exempt if disclosure of the document under this Act:

- (a) would, or could reasonably be expected to, cause damage to relations between the Commonwealth and a State (including a Territory)

47E Public interest conditional exemptions—certain operations of agencies

A document is conditionally exempt if its disclosure under this Act would, or could reasonably be expected to, do any of the following:

- (a) prejudice the effectiveness of procedures or methods for the conduct of tests, examinations or audits by an agency;
- (b) prejudice the attainment of the objects of particular tests, examinations or audits conducted or to be conducted by an agency;
- (c) have a substantial adverse effect on the management or assessment of personnel by the Commonwealth, by Norfolk Island or by an agency;
- (d) have a substantial adverse effect on the proper and efficient conduct of the operations of an agency.

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).

47F Public interest conditional exemptions—personal privacy

General rule

- (1) A document is conditionally exempt if its disclosure under this Act would involve the unreasonable disclosure of personal information about any person (including a deceased person).
- (2) In determining whether the disclosure of the document would involve the unreasonable disclosure of personal information, an agency or Minister must have regard to the following matters:
 - (a) the extent to which the information is well known;
 - (b) whether the person to whom the information relates is known to be (or to have been) associated with the matters dealt with in the document;
 - (c) the availability of the information from publicly accessible sources;
 - (d) any other matters that the agency or Minister considers relevant.
- (3) Subject to subsection (5), subsection (1) does not have effect in relation to a request by a person for access to a document by reason only of the inclusion in the document of matter relating to that person.

Access given to qualified person instead

- (4) Subsection (5) applies if:
 - (a) a request is made to an agency or Minister for access to a document of the agency, or an official document of the Minister, that contains information concerning the applicant, being information that was provided by a qualified person acting in his or her capacity as a qualified person; and
 - (b) it appears to the principal officer of the agency or to the Minister (as the case may be) that the disclosure of the information to the applicant might be detrimental to the applicant's physical or mental health, or well-being.
- (5) The principal officer or Minister may, if access to the document would otherwise be given to the applicant, direct that access to the document, so far as it contains that information, is not to be given to the applicant but is to be given instead to a qualified person who:
 - (a) carries on the same occupation, of a kind mentioned in the definition of **qualified person** in subsection (7), as the first-mentioned qualified person; and
 - (b) is to be nominated by the applicant.
- (6) The powers and functions of the principal officer of an agency under this section may be exercised by an officer of the agency acting within his or her scope of authority in accordance with arrangements referred to in section 23.
- (7) In this section:

qualified person means a person who carries on, and is entitled to carry on, an occupation that involves the provision of care for the physical or mental health of

people or for their well-being, and, without limiting the generality of the foregoing, includes any of the following:

- (a) a medical practitioner;
- (b) a psychiatrist;
- (c) a psychologist;
- (d) a counsellor;
- (e) a social worker.

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).

47G Public interest conditional exemptions—business

- (1) A document is conditionally exempt if its disclosure under this Act would disclose information concerning a person in respect of his or her business or professional affairs or concerning the business, commercial or financial affairs of an organisation or undertaking, in a case in which the disclosure of the information:
 - (a) would, or could reasonably be expected to, unreasonably affect that person adversely in respect of his or her lawful business or professional affairs or that organisation or undertaking in respect of its lawful business, commercial or financial affairs; or
 - (b) could reasonably be expected to prejudice the future supply of information to the Commonwealth, Norfolk Island or an agency for the purpose of the administration of a law of the Commonwealth or of a Territory or the administration of matters administered by an agency.
- (2) Subsection (1) does not apply to trade secrets or other information to which section 47 applies.
- (3) Subsection (1) does not have effect in relation to a request by a person for access to a document:
 - (a) by reason only of the inclusion in the document of information concerning that person in respect of his or her business or professional affairs; or
 - (b) by reason only of the inclusion in the document of information concerning the business, commercial or financial affairs of an undertaking where the person making the request is the proprietor of the undertaking or a person acting on behalf of the proprietor; or
 - (c) by reason only of the inclusion in the document of information concerning the business, commercial or financial affairs of an organisation where the person making the request is the organisation or a person acting on behalf of the organisation.
- (4) A reference in this section to an undertaking includes a reference to an undertaking that is carried on by, or by an authority of, the Commonwealth, Norfolk Island or a State or by a local government authority.
- (5) For the purposes of subsection (1), information is not taken to concern a person in respect of the person's professional affairs merely because it is information concerning the person's status as a member of a profession.

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).