

Commercial-in-confidence

Correspondence between Pfizer and the Department regarding the Public Summary Document (attachments provided in TRIM D24-1552269)

Type of correspondence	Department	Sponsor
HPP CORR027983	<p>15 September 2023</p> <p>Hello</p> <p>Please find attached a draft Public Summary Document (PSD) for your item.</p> <p>This PSD was prepared based on the PBAC Ratified Minutes from the July 2023 meeting, with redactions marked in grey. For full information on the standardised ranges and redactions for PSDs, please see the PSD Procedure Guidance.</p> <p>Requests for further redactions and/or disclaimers must be provided to the Department in writing by COB Friday 22 September 2023. The attached PSD will be published unless a response is received by this date. Please note:</p> <ul style="list-style-type: none"> • A single opportunity is provided for sponsors to review the PSD and seek redactions/disclaimers. • The request must clearly identify the specific content that is requested to be redacted (for example, any changes must be captured using track changes in the attached document; phrases should be highlighted in one colour which is not grey or black). • For each request, you must use the comment function to identify the redaction criteria (as specified in the PSD procedure guidance) supporting the request. Please provide any necessary evidence to support the requests, either in the document or as correspondence attachments. • Further information on how to appropriately request redaction of clinical data or inclusion of a disclaimer footnote, and information on the level of evidence required to support such requests is available at Appendix B - Supporting guidance for requesting a redaction to specific unpublished clinical data or including a disclaimer in a public summary document <p>When changes are agreed, the PBAC Secretariat will provide a final PSD prior to the publication date.</p> <p>For submissions made under the TGA–PBAC parallel process, PSDs for recommended or deferred items are prepared following standard timelines but are not published until TGA registration has occurred. It is the duty of the Sponsor to advise the department when TGA registration occurs. PSDs for not recommended items are prepared and published in accordance with the standard timeframes.</p> <p>For more information on PSD publication dates, please refer to the PBS Calendar.</p> <p>For questions relating to pricing offer packages and listing process, please</p>	<p>20 September 2023</p> <p>Dear PBAC Secretariat,</p> <p>Thank you very much for the opportunity to review the PSD and redaction of confidential information.</p> <p>As requested, I have highlighted the relevant information in yellow which requires redaction and left a corresponding comment with the rationales for redaction.</p> <p>I also provided you with an excel spreadsheet that demonstrates how it is easily possible to triangulate the ICER and subsequently allow calculation of the rimegepant price by using Table 12 and 13 of the Draft PSD. This is only one of many ways to perform the back calculation.</p> <p>Please do not hesitate to reach out if you have any questions.</p> <p>Kind regards,</p> <p>s47F</p>

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	<p>contact PBSpricing@health.gov.au.</p> <p>Kind Regards,</p> <p>PBAC Secretariat PBAC@health.gov.au Office of Health Technology Assessment Branch Technology Assessment and Access Division Department of Health and Aged Care GPO Box 9848, CANBERRA ACT 2601</p>	
HPP CORR027983	<p>12 October 2023</p> <p>Hello</p> <p>The public summary document (PSD) for the July 2023 PBAC meeting has been finalised for publication (attached).</p> <p>A version with comments/explanations from the Secretariat may also be attached where the applicant has requested additional redactions to those included in the draft.</p> <p>If an applicant does not agree with the final version of the PSD, the applicant may request an internal review (maximum one review per PSD).</p> <p>Internal review requests must be made in writing within three business days of receiving the final version of the PSD and must include the following:</p> <ul style="list-style-type: none"> • Rationale for requesting the review, and • Any additional evidence to support that review's delegate in making his/her final decision. <p>***Please note that the Department acknowledges that the final (for publication) version of the PSD has been sent earlier than usual (usually sent on Friday of Week 31). Should applicants have any internal review requests, the Department encourages applicants to send requests through within 3 business days of receiving the final version of the PSD. The Department would like to clarify that the standard timeline for internal review requests still remains for this cycle if the earlier date does not suit - that is COB Wednesday 18 October [Week 32].***</p> <p>Further information on how to appropriately request redaction of clinical data or inclusion of a disclaimer footnotes, and information on the level of evidence required to support such requests is available at Appendix B - Supporting guidance for requesting a redaction to specific unpublished clinical data or including a disclaimer in a public summary document. The PSD Procedure guidance is available at 7.4 Public Summary Documents.</p> <p>For submissions made under the TGA–PBAC parallel process, PSDs for recommended or deferred items are prepared following standard timelines but are not published until TGA registration has occurred. It is the duty of the Sponsor to advise the department when TGA</p>	<p>18 October 2023</p> <p>Dear PBAC Secretariat,</p> <p>We would like to request an Internal Review and ask the Department to reconsider its position with respect to Pfizer's requested redactions.</p> <p>Please find attached our letter outlining in detail our position and the rationales why redaction is required and in line with the Procedure Guidance for Public Summary Documents.</p> <p>Kind regards, s47F</p> <p>18 October 2023</p> <p>To whom it may concern Re: Rimegepant (Nurtec ODT) Public Summary Document (PSD) from July 2023 PBAC meeting (Agenda item 5.10)</p> <p>We refer to version 2 of the Draft PSD, and in particular the reference to Pfizer's economic analysis results in Table 12 s38 and Table 13 s38) of the draft PSD; specifically: s38 (together, the "Price Strategy Information").</p> <p>The Department has not agreed with Pfizer's view that the Draft PSD contains information which effectively discloses the Price Strategy Information. Pfizer does not agree with the Department's assessment and requests an Internal Review of the PSD pursuant to section 7.4.1 of the Procedure Guidance for Public Summary Documents.</p> <p>We maintain that the Price Strategy Information is "confidential financial and cost information" which is "involved in generating" the ICERs or other measure of the estimated cost-effectiveness referred to throughout the PSD, which, accordingly, should be redacted from the PSD (as per section 7.4.1 of the PSD Procedure Guidance).</p>

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registration occurs. PSDs for not recommended items are prepared and published in accordance with the standard timeframes.

For more information on PSD publication dates, please refer to the [PBS Calendar](#).

Kind regards,

PBAC Secretariat
Office of Health Technology Assessment Branch
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: PBAC@health.gov.au
PO Box 9848, Canberra ACT 2601, Australia

Pfizer set out our reasoning for treating the Price Strategy Information as confidential in our response on 20/09/2023 to version 1 of the Draft PSD provided by the Department on 15/09/2023. In summary, we stated and repeat that:

- The Price Strategy Information can be **specifically identified** using the detailed information presented in Table 12 and Table 13, allowing the stepwise back-calculation of the price per pack and tablet as proposed by Pfizer in the March 2023 submission. In our response to version 1 Draft PSD we provided the Department with calculations demonstrating that it is feasible to undertake a price calculation based on the information presented in Table 12 and Table 13, such calculation which can identify Pfizer's effective DPMQ within a narrow price range. By disclosing a close estimate of Pfizer's confidential price, the Draft PSD reveals sensitive information which could benefit Pfizer's competitors, and as noted below, irreparably harm Pfizer. For ease of reference, a summary of the back-calculation has been provided in Appendix 1 of this document.
- The Price Strategy Information has the **necessary quality of confidence**, in that it has a degree of secrecy in specifically identifying Pfizer's pricing strategy on the effective DPMQ as presented to the PBAC by Pfizer on an expressly confidential basis. Further, such pricing proposals and strategy are **neither in the public domain, nor are they public knowledge**.
- The proposed effective DPMQ, from which the Price Strategy Information was wholly derived, was provided by Pfizer, and received by the PBAC, in circumstances that both parties have previously, and would currently have understood **created an obligation of confidence**, considering the confidential quality of such information as set out immediately above.
- Publication of the Price Strategy Information would be an **unauthorised use** of such information, considering that the Price Strategy Information was provided to the PBAC for the purpose of assisting the PBAC to assess the cost-effectiveness and budget impact of Zimegepant. Publication of the Price Strategy Information has the potential to cause **irreparable harm to Pfizer's business**, both in Australia and internationally. The disclosure of the Price Strategy Information also has the potential to harm Pfizer's global business from a global reference pricing perspective.

Further, redaction of the Price Strategy Information is consistent with addressing industry concerns to "protect commercially sensitive information while meeting the PBAC objectives to make all clinical evidence available", as per the Statement of Endorsement: Improving the Transparency of PBAC Outcomes.

We, therefore, request an Internal Review and ask the Department to reconsider its position with respect to the Price Strategy Information, and respectfully insist that Pfizer's requested redactions be incorporated prior to publication.

Finally, we request that the Department provide Pfizer the opportunity to respond to the findings of the Internal Review prior to publication of the final PSD, such that Pfizer is afforded an opportunity to take appropriate steps to protect its confidential information if the PSD will disclose, directly or indirectly, the Price Strategy Information.

Yours sincerely,

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		s47F
HPP CORR028908	<p>23 October 2023</p> <p>Good afternoon</p> <p>The Department has conducted an internal review for your item. Upon further consideration, the Department does not accept redaction of incremental QALYs, cost of PBO/BSC for Table 12 and incremental QALYs for Table 13. However, the Department proposes to redact the % change from base case in Table 13. One will not be able to triangulate the base-ICER, incremental cost and thus the price of the medication without the % change from base case.</p> <p>Please find attached the draft and final PSDs for your review. If no response is received by COB Tues 24 October, the attached final PSD will be published.</p> <p>Thank you, s22 PBAC Secretariat</p>	<p>24 October 2023</p> <p>s2 Dea 2 at PBAC Secretariat,</p> <p>Thank you for the opportunity to review and comment on V3 of the PSD. Pfizer is accepting the proposal to redact the percentage change from the baseline ICER in the last column of Table 13 in the PSD. However, I noted that the percentage change numbers were not redacted in V3 of the draft PSD and I kindly request for an updated version (clean and tacked) prior to publishing the PSD. I tracked the redaction in the supporting document as an attachment.</p> <p>In addition, I appreciate that QALY and incremental QALY are aimed to be published by the PBAC/Secretariat, however, publishing QALY data up to 6 decimal places as done in Table 12 Step 2 of the draft PSD is unintentionally disclosing very sensitive confidential commercial information, especially since the ICER ranges of s38 combined with the incremental QALY number of 6 decimal places allows very close estimation of the true effective DPMQ price range as demonstrated in Pfizer's Letter to V2 draft PSD (Step 3). Therefore, publication of the QALY and incremental QALY numbers in Step 2 of Table 12 of the Draft PSD should be aligned with Step 3 and 4 of Table 12, which is limited to 4 decimal places. This would allow less precise estimations of the effective DPMQ. As outlined in Pfizer's Letter to V2 of the draft PSD, each step provides opportunity to estimate the effective DPQM, triangulation using Table 13 and calculation of ranges using Table 12, and combining the methods allows narrowing down ranges substantially. Therefore, only redaction of Table 13 percentage ranges limits the price estimation somewhat, but Table 12 Step 2 still would allow to generate detailed base ranges close to effective DPMQ by providing QALY and incremental QALY in 6 decimal places. Please carefully consider the proposal on 4 decimal places since it does mitigate disclosing confidential commercial information.</p> <p>Kind regards, s47F</p>
HPP CORR029022	<p>25 October 2023</p> <p>Good afternoon s47F</p> <p>The Department has considered your concerns and does not accept your request for redaction of QALYs of up to 4 decimals in Step 2 of Table 12. The QALY values, as presented up to 6 decimals in Table 12 will be published as is. The final redacted copy of the PSD is attached for your reference.</p> <p>The argument of back-calculation is not valid when the exact price is not revealed. As the ICERs have been replaced with ranges, the price of the rimegepant can only be calculated as a range, as presented by the sponsor's calculation in Step 3 of the Letter. Please note that the ICER ranges were agreed with the industry and have been applied fairly to all PSDs.</p>	

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The QALY of §47(1)(b) yields a price range of §47(1)(b) whereas the QALY of §47(1)(b) yields a price range of §47(1)(b). Your request to redact the QALY data up to 4 decimals is not reasonable when the difference is only §47(1)(b). Further, the difference of the estimated price ranges is the same as the difference in the ICER range, which equals to a total of §47(1)(b).

QALY	ICER	% difference in the ICER range	Estimated price	% difference in the estimated price
§47(1)(b)	115,000	§47(1)(b)		
	135,000			
	115,000			
	135,000			

The attached final PSD will therefore be published as scheduled if no response is received by **10am tomorrow**.

Thank you,
§22
PBAC Secretariat

Email

From: §47F @pfizer.com>

Sent: Thursday, October 26, 2023 4:49 PM

To: PBAC <PBAC@health.gov.au>

Cc: §47F @pfizer.com>

Subject: RE: In relation to CORR029022 [HPP005391] - PSD Review [SEC=OFFICIAL]

Hi §22

Many thanks for the swift response and guidance on the correspondence process. I indeed was required to open a new correspondence. However, I wasn't able to select 'PSD review' in the drop down since that option wasn't available, so I selected 'Committee Secretariat' instead since the other options didn't quite fit.

Also, please find below my signature our response to CORR029022, just in case something went awry in the portal.

Best Wishes,
§47F

Thank you for your response.

We understand from your message that an Internal Review of our request has been undertaken further to our letter dated 18 October 2023.

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We respectfully disagree with the approach taken by the Department with respect to the disclosure of effective price range data utilising Table 12 Step 2 of the PSD.

In Section 7.4.1 of the Public Summary Document, the Department is obliged to "**redact any related confidential financial and cost information** within the PSD that is **not related to clinical data**". In this instance, the QALY values in Table 12 are related to cost effectiveness data to derive the price, and not clinical data. This data therefore requires redaction.

Furthermore, the purpose of the PSD is to provide the public with information pertaining to PBAC recommendations, so that stakeholders are aware of the rationale for specific PBAC recommendations, and gain an improved understanding of the overall PBS listing. [reference 1]

The redaction of the QALY values does not inhibit stakeholders from understanding the rationale for the PBAC's recommendation.

Pfizer does not agree with the Department's approach that a narrow range can be disclosed without specifying the exact confidential price. This approach is not what Industry and the Department intended when the Industry Agreement was developed, as on the Department's basis a price range of a few cents could be published. The Department's approach therefore has the effect of disclosing Pfizer's price, which was disclosed to the PBAC on a confidential basis (pursuant to s.135A of the National Health Act), and has potential to harm Pfizer's commercial interests.

Confidential pricing is only disclosed by sponsors for the purposes of **evaluation and consideration of the PBAC submission**, and in preparation of a Special Pricing Agreement (as further detailed in "The Deed of Agreement Process"). [reference 2]

We therefore request again that the QALY values in Table 12 Step 2 of the draft PSD are fully redacted prior to publication, as requested in our Letter from the 18 October 2023.

Pfizer would consider a failure to do so a breach of the confidentiality **obligations of those who are privy to data included in PBAC submissions**.

In respect of the Internal Review, we request confirmation of a statement of grounds outlining the reasons for the Department's decision, including why the Department is not following the requirements of Section 7.4.1 of the PSD.

Kind regards,

s47F

References:

1. Public Summary Document Explained - <https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd/pbac-psd-psd-explained>

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		2. The Deed of Agreement Process - https://www.pbs.gov.au/pbs/industry/listing/elements/deeds-agreement/c-deed-of-agreement
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THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH AND AGED CARE



18 October 2023

PBAC Secretariat
Office of Health Technology Assessment Branch
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: PBAC@health.gov.au
PO Box 9848, Canberra ACT 2601, Australia

To whom it may concern

Re: Rimegepant (Nurtec ODT) Public Summary Document (PSD) from July 2023 PBAC meeting (Agenda item 5.10)

We refer to version 2 of the Draft PSD, and in particular the reference to Pfizer's economic analysis results in Table 12 ^{s38} and Table 13 ^{s38} of the draft PSD; specifically:

- detailed presentation of the quality-adjusted life years (QALY) values and the costs of best-supportive care (BSC) in Table 12, and the incremental QALY values in Table 13.

(together, the "Price Strategy Information").

The Department has not agreed with Pfizer's view that the Draft PSD contains information which effectively discloses the Price Strategy Information. Pfizer does not agree with the Department's assessment and requests an Internal Review of the PSD pursuant to section 7.4.1 of the Procedure Guidance for Public Summary Documents.

We maintain that the Price Strategy Information is "confidential financial and cost information" which is "involved in generating" the ICERs or other measure of the estimated cost-effectiveness referred to throughout the PSD, which, accordingly, **should be redacted from the PSD** (as per section 7.4.1 of the PSD Procedure Guidance).

Pfizer set out our reasoning for treating the Price Strategy Information as confidential in our response on 20/09/2023 to version 1 of the Draft PSD provided by the Department on 15/09/2023. In summary, we stated and repeat that:

- The Price Strategy Information can be **specifically identified** using the detailed information presented in Table 12 and Table 13, allowing the stepwise back-calculation of the price per pack and tablet as proposed by Pfizer in the March 2023 submission. In our response to version 1 Draft PSD we provided the Department with calculations demonstrating that it is feasible to undertake a price calculation based on the information presented in Table 12 and Table 13, such calculation which can identify Pfizer's effective DPMQ within a narrow price range. By disclosing a close estimate of Pfizer's confidential price, the Draft PSD reveals sensitive information which could benefit Pfizer's competitors, and as noted below, irreparably

harm Pfizer. For ease of reference, a summary of the back-calculation has been provided in Appendix 1 of this document.

- The Price Strategy Information has the **necessary quality of confidence**, in that it has a degree of secrecy in specifically identifying Pfizer's pricing strategy on the effective DPMQ as presented to the PBAC by Pfizer on an expressly confidential basis. Further, such pricing proposals and strategy are **neither in the public domain, nor are they public knowledge**.
- The proposed effective DPMQ, from which the Price Strategy Information was wholly derived, was provided by Pfizer, and received by the PBAC, in circumstances that both parties have previously, and would currently have understood **created an obligation of confidence**, considering the confidential quality of such information as set out immediately above.
- Publication of the Price Strategy Information would be an **unauthorised use** of such information, considering that the Price Strategy Information was provided to the PBAC for the purpose of assisting the PBAC to assess the cost-effectiveness and budget impact of Zimegepant. Publication of the Price Strategy Information has the potential to cause **irreparable harm to Pfizer's business**, both in Australia and internationally. The disclosure of the Price Strategy Information also has the potential to harm Pfizer's global business from a global reference pricing perspective.

Further, redaction of the Price Strategy Information is consistent with addressing industry concerns to "protect commercially sensitive information while meeting the PBAC objectives to make all clinical evidence available", as per the Statement of Endorsement: Improving the Transparency of PBAC Outcomes.

We, therefore, request an Internal Review and ask the Department to reconsider its position with respect to the Price Strategy Information, and respectfully insist that Pfizer's requested redactions be incorporated prior to publication.

Finally, we request that the Department provide Pfizer the opportunity to respond to the findings of the Internal Review prior to publication of the final PSD, such that Pfizer is afforded an opportunity to take appropriate steps to protect its confidential information if the PSD will disclose, directly or indirectly, the Price Strategy Information.

Yours sincerely,

s47F



s22

From: s47F [REDACTED]@pfizer.com>
Sent: Thursday, 26 October 2023 4:49 PM
To: PBAC
Cc: s47F [REDACTED]
Subject: RE: In relation to CORR029022 [HPP005391] - PSD Review [SEC=OFFICIAL]

Categories: Outcomes Team

Hi s22

Many thanks for the swift response and guidance on the correspondence process. I indeed was required to open a new correspondence. However, I wasn't able to select 'PSD review' in the drop down since that option wasn't available, so I selected 'Committee Secretariat' instead since the other options didn't quite fit.

Also, please find below my signature our response to CORR029022, just in case something went awry in the portal.

Best Wishes,
 s47F [REDACTED]

Thank you for your response.

We understand from your message that an Internal Review of our request has been undertaken further to our letter dated 18 October 2023.

We respectfully disagree with the approach taken by the Department with respect to the disclosure of effective price range data utilising Table 12 Step 2 of the PSD.

In Section 7.4.1 of the Public Summary Document, the Department is obliged to "**redact any related confidential financial and cost information** within the PSD that is **not related to clinical data**". In this instance, the QALY values in Table 12 are related to cost effectiveness data to derive the price, and not clinical data. This data therefore requires redaction.

Furthermore, the purpose of the PSD is to provide the public with information pertaining to PBAC recommendations, so that stakeholders are aware of the rationale for specific PBAC recommendations, and gain an improved understanding of the overall PBS listing. [reference 1]

The redaction of the QALY values does not inhibit stakeholders from understanding the rationale for the PBAC's recommendation.

Pfizer does not agree with the Department's approach that a narrow range can be disclosed without specifying the exact confidential price. This approach is not what Industry and the Department intended when the Industry Agreement was developed, as on the Department's basis a price range of a few cents could be published. The Department's approach therefore has the effect of disclosing Pfizer's price, which was disclosed to the PBAC on a confidential basis (pursuant to s.135A of the National Health Act), and has potential to harm Pfizer's commercial interests.

Confidential pricing is only disclosed by sponsors for the purposes of **evaluation and consideration of the PBAC submission**, and in preparation of a Special Pricing Agreement (as further detailed in "The Deed of Agreement Process"). [reference 2]

We therefore request again that the QALY values in Table 12 Step 2 of the draft PSD are fully redacted prior to publication, as requested in our Letter from the 18 October 2023.

Pfizer would consider a failure to do so a breach of the confidentiality **obligations of those who are privy to data included in PBAC submissions.**

In respect of the Internal Review, we request confirmation of a statement of grounds outlining the reasons for the Department's decision, including why the Department is not following the requirements of Section 7.4.1 of the PSD.

Kind regards,

s47F

References:

1. Public Summary Document Explained - <https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd/pbac-psd-psd-explained>
2. The Deed of Agreement Process - <https://www.pbs.gov.au/pbs/industry/listing/elements/deeds-agreement/c-deed-of-agreement>

From: PBAC <PBAC@health.gov.au>

Sent: Thursday, 26 October 2023 10:52 AM

To: s47F @pfizer.com>

Cc: PBAC <PBAC@health.gov.au>; s47F @pfizer.com>

Subject: [EXTERNAL] RE: In relation to CORR029022 [HPP005391] - PSD Review [SEC=OFFICIAL]

Dear s47F

Thank you for your email. Given your concerns, in this instance the Department accepts your request for extension until 5pm AEDT today, 26 October 2023.

Please note, to respond in the HPP you may be required to initiate a new correspondence. If so, please endeavour to choose the correspondence category of "PSD review".

Kind Regards,

s22

PBAC Secretariat

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: PBAC@health.gov.au
GPO Box 9848, Canberra ACT 2601

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s47F @pfizer.com>

Sent: Thursday, 26 October 2023 10:08 AM

To: PBAC <PBAC@health.gov.au>

Cc: s47F @pfizer.com>

Subject: In relation to CORR029022 [HPP005391] - PSD Review

Importance: High

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.

Good morning s2 and team,

I understand that a deadline of 10am this morning was set for comments on the PSD.

I would be grateful if we could respond by end of the day today, considering the potential disclosure of price sensitive information posing a risk to Pfizer.

Many thanks,
s47F

s47F

Pfizer Australia

Mob : s47F : Level 15-18/151 Clarence Street, Sydney NSW 2000 www.pfizer.com.au



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BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

From: s22
Sent: Friday, 29 September 2023 2:31 PM
To: s22
Cc: s22
Subject: RE: For advice by COB Weds 3 Oct: 5.10 rimegepant PSD [SEC=OFFICIAL]

Hi all,

My responses are below in red – I agree with your position in all the situations.

Cheers,
 s22

From: s22 @Health.gov.au>
Sent: Thursday, 28 September 2023 4:03 PM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @Health.gov.au>
Subject: For advice by COB Weds 3 Oct: 5.10 rimegepant PSD [SEC=OFFICIAL]

Hi s22 and s22

I am current drafting 5.10 rimegepant PSD from July 2023 PBAC meeting and would be grateful for your advice of the following sponsor's requests. I've attached the PSD for your reference. Would be grateful for your response by **COB Weds Oct 3**.

- 1. Table 12 and 13** – Sponsor requested the QALY results (highlighted yellow) to be redacted as it allows back-calculation of the rimegepant price using ICER ranges. Sponsor has also submitted a workbook where they demonstrated their calculation (saved [here](#)). s47C

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Below are FYI. Let me know if you do not agree with any of our approaches.

3. Table 5, 6, 9 and 10; para 6.51 – Sponsor requested these unpublished data to be redacted. s47C

		s22
5.10 rimegepant	s38	<p>Dept: Redaction not accepted. Under the procedure guidance, the Department considers redaction requests to clinical data under 3 criteria – the applicant has not identified which of these criteria applies. More information regarding the required level of justification is available at Appendix B to the Procedure Guidance. https://www.pbs.gov.au/info/industry/listing/procedure-guidance/appendix-b</p> <p>In this case, it was assumed that the sponsor was requesting redaction under the 1st criteria where data is from a clinical study for which <u>no results at all</u> would have entered the public domain at the time of publishing the PSD, and the applicant is able to demonstrate both that the publication of the information in the PSD would prevent the publication of any results from this study elsewhere, and also that there is a documented requirement external to the applicant that these results (with or without other results) of the clinical study are to be published once they have been more completely generated.</p> <p>More information about the redaction criteria is available at https://www.pbs.gov.au/info/industry/listing/procedure-guidance/7-post-pbac-decision-procedures-sponsors/7-4-public-summary-documents</p> <p>In saying this, for the redaction request to be accepted, the sponsor will need to provide evidence that publication of the information in the PSD would prevent the publication of any results from this study elsewhere, and also that there is a documented requirement external to the applicant that these results (with or without other results) of the clinical study are to be published once they have been more completely generated.</p>

	s22	
s22	<div data-bbox="206 740 407 774">5.10 rimegepant</div> <div data-bbox="734 475 1505 1190">THIS DOCUMENT HAS BEEN RELEASED UNDER THE FREEDOM OF INFORMATION ACT 1982 BY THE DEPARTMENT OF HEALTH AND AGED CARE</div>	

s22

Subject: PSD Internal review - 5.10 Rimegepant, s22 [SEC=OFFICIAL]
Location: webex

Start: Mon 23/10/2023 10:30 AM
End: Mon 23/10/2023 11:00 AM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: s22
Required Attendees: s22

Hi s22

We received two internal review requests for 5.10 Rimegepant (Table 12 & 13) and s22 where sponsors requested for redaction of incremental QALYs from their Stepped economic evaluation and Sensitivity analyses tables as data presented can be used to triangulate the base-ICERs and incremental costs.

My team has done further calculations and can confirm that we should be redacting the % change (found in Sensitivity analyses table) rather than the sponsor's proposed incremental QALYs to prevent back-calculation. One could still easily triangulate to the base- ICER and incremental cost if we redact the incremental QALYs and not the % change. Once the base-ICER and incremental cost are established, this allows back-calculation to the price of the medication (not exact but the difference is very small).

In this meeting, we would like to show you how the calculations are done and discuss the broader implications of our approaches to redacting these tables in the PSDs.

In this email, I've attached the following:

1. 5.10 Rimegepant V2 PSD
2. s22
3. 5.10 Rimegepant & s22 calculations  [Rimegepant and s22 calculations.xlsx](#)

Please let us know if this proposed time does not suit.

Chat soon.

s22

Outcomes Team

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

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<https://health-au.webex.com/s22>

Join by meeting number

Meeting number (access code): s22

Meeting password: s22

Tap to join from a mobile device (attendees only)

s22 Australia Toll

Join by phone

s22 Australia Toll

[Global call-in numbers](#)

Join from a video system or application

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Need help? Go to <https://help.webex.com>

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s22

From: s22
Sent: Monday, 23 October 2023 5:02 PM
To: s22
Cc: s22; s22
Subject: RE: s22 and 5.10 rimegepant IR responses [SEC=OFFICIAL]

Thanks for getting back to us s22 We will finalise and send back to sponsor accordingly.

Cheers,
s22

From: s22 @health.gov.au>
Sent: Monday, 23 October 2023 4:30 PM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: s22 and 5.10 rimegepant IR responses [SEC=OFFICIAL]

Hi s22

I'm happy with the Pfizer response.

For the s22 response I've proposed some changes (highlighted below).

Cheers

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

This email comes to you from Ngunnawal Country
PO Box 9848, Canberra ACT 2601, Australia
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @Health.gov.au>
Sent: Monday, 23 October 2023 12:45 PM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: s22 and 5.10 rimegepant IR responses [SEC=OFFICIAL]

Hi s22

Please see our proposed responses for both s22 and 5.10 rimegepant for your review. The V3 Drafts for both PSDs are attached for your reference.

Thanks,
s22

Item	Sponsor's internal review request	Dept's response
------	-----------------------------------	-----------------

s22

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5.10 Rimegepant	Table 12 Economic evaluation: Sponsor requested redaction of QALYs and cost of PBO/BSC	Good afternoon
--------------------	-----------------------------------------------------------------------------------------------	-------------------

s38

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The Department has conducted an internal review for your item. Upon further consideration, the Department does not accept redaction of QALYs, cost of PBO/BSC for Table 12 and incremental QALYs for Table 13. However, the Department proposes to redact the % change from base case in Table 13. One will not be able to triangulate the base-ICER, incremental cost and thus the price of the medication without the % change from base case.

Please find attached the draft and final PSDs for your review. If no response is received by COB Tues 24 October, the attached final PSD will be published.

Thank you,
s22

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BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

From: s22
Sent: Wednesday, 25 October 2023 10:58 AM
To: s22
Cc: s22
Subject: RE: For review: Further IR request for 5.10 rimegepant [SEC=OFFICIAL]

Cleared to go, well done team!

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @Health.gov.au>
Sent: Tuesday, 24 October 2023 2:48 PM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: For review: Further IR request for 5.10 rimegepant [SEC=OFFICIAL]

Hi s22

As discussed, we will reject Pfizer's further request for redaction of QALY in Table 12 (see snapshot 1 at the end of the email). Draft response attached below for your review.

Thank you,
 s22

Good afternoon s47F

The Department has considered your concerns and does not accept your request for redaction of QALYs of up to 4 decimals in Step 2 of Table 12. The QALY values, as presented up to 6 decimals in Table 12 will be published as is. The final redacted copy of the PSD is attached for your reference.

The argument of back-calculation is not valid when the exact price is not revealed. As the ICERs have been replaced with ranges, the price of the rimegepant can only be calculated as a range, as presented by the sponsor's calculation in Step 3 of the Letter s22 **I've attached Pfizer's letter and a snapshot of Step 3 at the end of the email for your reference**). Please note that the ICER ranges were agreed with the industry and have been applied fairly to all PSDs.

The QALY of s47(1)(b) yields a price range of s47(1)(b) whereas the QALY of s47(1)(b) yields a price range of s47(1)(b). Your request to redact the QALY data up to 4 decimals is not reasonable when the difference is s47(1)(b). Further, the difference of the estimated price ranges is the same as the difference in the ICER range, which equals to a total of s47(1)(b).

QALY	ICER	% difference in the ICER range	Estimated price	% difference in the estimated price
s47(1)(b)	115,000	s47(1)(b)		
	135,000			
	115,000			
	135,000			

The attached final PSD will therefore be published as scheduled if no response is received by **12pm tomorrow.**

Thank you,

s22

PBAC Secretariat


Snapshot 1 of Pfizer's further concerns

s38

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Snapshot 2: Step 3 of the Pfizer Letter

s47(1)(b)



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s22

From: s22
Sent: Thursday, 26 October 2023 10:41 AM
To: s22
Cc: s22
Subject: RE: 5.10 Rimegepant FW: In relation to CORR029022 [HPP005391] - PSD Review [SEC=OFFICIAL]

No problem, thanks s22

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @Health.gov.au>
Sent: Thursday, 26 October 2023 10:40 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: 5.10 Rimegepant FW: In relation to CORR029022 [HPP005391] - PSD Review [SEC=OFFICIAL]
Importance: High

Hi s22

In the absence of s22 until 12pm, would you please be able to confirm if you are happy with the proposed action and response?

Pfizer have requested longer to respond to the final PSD we sent yesterday afternoon. (Please see forwarded email below).

I propose to accept the request as negative PSDs will not be published until Nov 10.

Proposed response

Dear s47F

Thank you for your email. Given your concerns, in this instance the Department accepts your request for extension until 5pm AEDST today, 26 October 2023.

Thank you
 PBAC Secretariat

Kind Regards,

s22

PBAC Assessment Section
 Technology Assessment & Access Division | Health Resourcing Group

Australian Government Department of Health and Aged Care
 E s22 @health.gov.au

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s47F @pfizer.com>
Sent: Thursday, 26 October 2023 10:08 AM
To: PBAC <PBAC@health.gov.au>
Cc: s47F @pfizer.com>
Subject: In relation to CORR029022 [HPP005391] - PSD Review
Importance: High

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.

Good mornin s22 and team,

I understand that a deadline of 10am this morning was set for comments on the PSD.

I would be grateful if we could respond by end of the day today, considering the potential disclosure of price sensitive information posing a risk to Pfizer.

Many thanks,
 s47F

s47F

s47F, Pfizer Australia

Mob : s47F : Level 15-18/151 Clarence Street, Sydney NSW 2000 www.pfizer.com.au



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s22

From: s22
Sent: Thursday, 26 October 2023 1:37 PM
To: s22
Subject: Draft options for s22 For advice by 11am: 5.10 rimegepant [SEC=OFFICIAL]

Hi s22 and s22

I've drafted some proposed options with draft response in case Pfizer argues further. Feel free to make edits in the email below and send it back to me by COB today.

Thanks,
s22

Hi s22

Pfizer reiterated that they are disappointed and requested that we reconsider their request to redact the incremental QALY up to 4 decimals in Step 2 of Table 12.

We have proposed some options with draft response for your advice at the end of this email. Would be grateful for your advice by **11 am tomorrow**. I've also attached the V3 draft we sent to sponsor previously.

Pfizer's response

XX

Proposed options with draft response for your consideration

Options	Benefits	Risks	Draft response
s47C			

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Proposed redactions for Option A

1. Table 12

s38



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s22

From: s22
Sent: Friday, October 27, 2023 9:52 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: Options for response: For advice by 11am - 5.10 rimegepant [SEC=OFFICIAL]

Will do, we will refine our draft approach this morning and send to LAD.

Thanks

s22 *[She/Her]*
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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 PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @health.gov.au>
Sent: Friday, 27 October 2023 9:50 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: Options for response: For advice by 11am - 5.10 rimegepant [SEC=OFFICIAL]

Hi s22

Yes I think that would be helpful, are you able to request this from LAD? Can you request that the advice be given in a timeframe that won't cause any delay to PSD publication?

Thanks

s22

s22

Acting Assistant Secretary, Office of Health Technology Assessment (OHTA)

Technology Assessment and Access Division (TAAD), Australian Government Department of Health & Aged Care

T: 02 6289 s22

E: s22 @health.gov.au

Location: Sirius 9.N.118

PO 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: s22 @health.gov.au>
Sent: Friday, 27 October 2023 9:45 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: FW: Options for response: For advice by 11am - 5.10 rimegepant [SEC=OFFICIAL]

Hi s22

We have been back and forth with Pfizer again on this PSD. Given the language of Pfizer's request for confirmation of a statement of grounds outlining the reasons for the Internal Review decision, do you think it would be appropriate that we seek legal review of a draft response? It's a batch 2 PSD so we have a little time.

Thanks

s22 [She/Her]
 Director – PBAC Assessment Section
 Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: s22 @Health.gov.au>
Sent: Thursday, 26 October 2023 8:32 PM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: Options for response: For advice by 11am - 5.10 rimegepant [SEC=OFFICIAL]

Hi s22

Please see below Pfizer's response regarding 5.10 rimegepant. Pfizer reiterated their stance and requested that we reconsider their request to redact the QALY values in Table 12. As highlighted below, Pfizer seems to be requesting for the QALY values to be fully redacted in Table 12 now. Pfizer previously requested for the QALY values to be redacted up to 4 decimals.

We have proposed some options with draft response for your advice at the end of this email. Would be grateful for your advice by **11 am tomorrow**. I've also attached the V3 draft we sent to sponsor previously and the Pfizer Letter for your reference.

Thank you,

s22

Pfizer's response

Thank you for your response.

We understand from your message that an Internal Review of our request has been undertaken further to our letter dated 18 October 2023.

We respectfully disagree with the approach taken by the Department with respect to the disclosure of effective price range data utilising Table 12 Step 2 of the PSD.

In Section 7.4.1 of the Public Summary Document, the Department is obliged to "redact any related confidential financial and cost information within the PSD that is not related to clinical data". In this instance, the QALY values in Table 12 are related to cost effectiveness data to derive the price, and not clinical data. This data therefore requires redaction.

Furthermore, the purpose of the PSD is to provide the public with information pertaining to PBAC recommendations, so that stakeholders are aware of the rationale for specific PBAC recommendations, and gain an improved understanding of the overall PBS listing. [reference 1]

The redaction of the QALY values does not inhibit stakeholders from understanding the rationale for the PBAC's recommendation.

Pfizer does not agree with the Department's approach that a narrow range can be disclosed without specifying the exact confidential price. This approach is not what Industry and the Department intended when the Industry Agreement was developed, as on the Department's basis a price range of a few cents could be published. The Department's approach therefore has the effect of disclosing Pfizer's price, which was disclosed to the PBAC on a confidential basis (pursuant to s.135A of the National Health Act), and has potential to harm Pfizer's commercial interests.

Confidential pricing is only disclosed by sponsors for the purposes of evaluation and consideration of the PBAC submission, and in preparation of a Special Pricing Agreement (as further detailed in "The Deed of Agreement Process"). [reference 2]

We therefore request again that the QALY values in Table 12 Step 2 of the draft PSD are fully redacted prior to publication, as requested in our Letter from the 18 October 2023.

Pfizer would consider a failure to do so a breach of the confidentiality obligations of those who are privy to data included in PBAC submissions.

In respect of the Internal Review, we request confirmation of a statement of grounds outlining the reasons for the Department's decision, including why the Department is not following the requirements of Section 7.4.1 of the PSD.

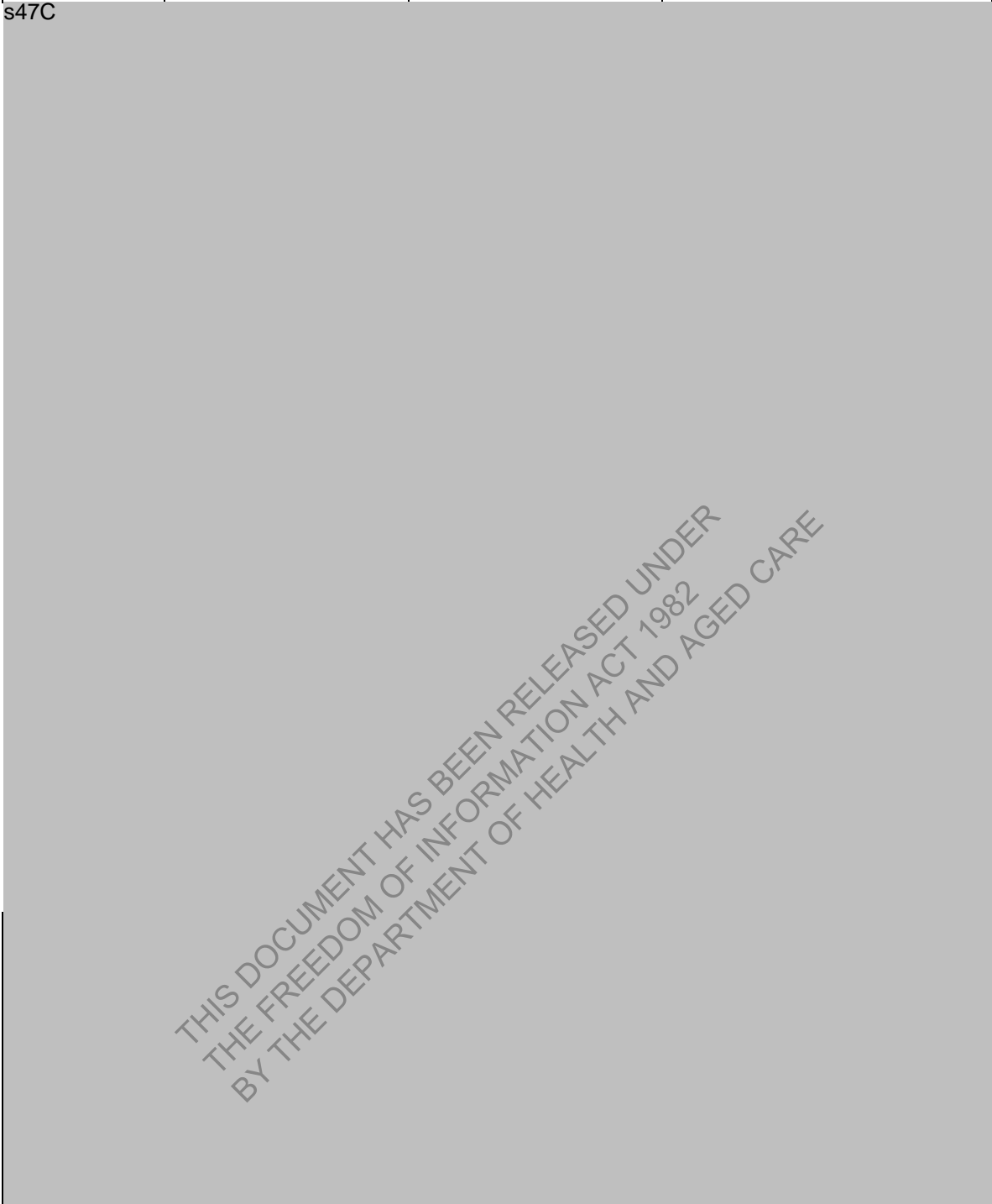
Kind regards,

s47F

References:

- Public Summary Document Explained - <https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd/pbac-psd-psd-explained>
- The Deed of Agreement Process - <https://www.pbs.gov.au/pbs/industry/listing/elements/deeds-agreement/c-deed-of-agreement>


Proposed options with draft response for your consideration

Options	Benefits	Risks	Draft response
s47C			

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Proposed redactions for Option A

1. Table 12 – redacting cost of PBO/BSC

s38	
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2. Table 10 – redacting cost of placebo

s38



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s22

From: s22
Sent: Monday, 30 October 2023 10:35 AM
To: s22
Cc: s22
Subject: RE: For review: LAD advice required - rimegepant public summary document PBAC [SEC=OFFICIAL]

Hi all

Great job on this difficult draft, I only changed one line that didn't quite make sense:

The ICER ranges that are used in PSDs were agreed to by industry and were have been used consistently across all PSDs.

to

The ICER ranges were agreed to by industry and are used consistently across all PSDs.

Many thanks

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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 PO Box 9848, Canberra ACT 2601, Australia

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From: s22 @health.gov.au>
Sent: Friday, 27 October 2023 9:59 PM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: For review: LAD advice required - rimegepant public summary document PBAC [SEC=OFFICIAL]

Hi s22

Please see draft email to LAD with proposed draft response to Pfizer for your review.

Thank you to s22 for running me through all the background and thanks to those who contributed to the draft.

Thanks

s22

s42

Thanks s22

s22 appreciate if you can action.

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

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Hi s22

13

Regards,

s22
Finance Business Partner
Technology Assessment and Access Division, Health Financing Group

Financial Management Division | COO Group
Financial Business Support Branch
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
Location: Sirius Building s22

From: s22 @health.gov.au>
Sent: Friday, 3 November 2023 11:20 AM
To: s47E(d) @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: s42
[SEC=OFFICIAL, ACCESS=Legal-Privilege]
Importance: High

Hi s22

Please confirm funds availability for the below ASAP.

Many thanks

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: s22 @Health.gov.au>
Sent: Friday, 3 November 2023 10:00 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: FW: s42
[SEC=OFFICIAL, ACCESS=Legal-Privilege]
Importance: High

Good morning s22 and team,

Please see the below email from AGS setting out their preliminary quote for this work. AGS have initially quoted estimate \$16,900 (GST excl) noting that they are keen to meet with you to discuss this matter and obtain further instructions as soon as possible. We consider the quote represents value for money.

We would be grateful if you could undertake the highlighted steps below as soon as possible so we can progress this work. If you have any questions, please call me.

Step 1 - LAD lawyer – to complete the table below and forward to the Project Officer along with the law firm quotation and Request for Quote (please include quotation in email trail, not as an attachment)

LEX ID:	46880
Purchase order number:	
LAD lawyer:	s22
Commitment Type:	New
Law firm lawyer name:	s22
Law firm lawyer email:	s22 @ags.gov.au
NEW Order expiry date:	30 November
Total Order value (incl. any variation):	\$16,900 (excl GST)

Step 2 - Project Officer in line area – to complete the table below and then forward email to the relevant Finance Business Partner (FBP)

Finance Business Partner:	s22		
Division:	TAAD		
Cost Centre:	s47E(d)		
Delegate name:	s22 (EL2)		
Note: For variations, delegation level must be for the total value including the variation. Current financial delegations are available on the intranet . As of 29 November 22 they are:			
Department wide classification	Summary of power or function	Administered Funds	Departmental Funds
Division Head / FAS / SES B2	PGPA Act s23 (3) To approve proposals to commit relevant money	\$100m	\$10m
Branch Head / AS / SES B1		\$50m	\$1m
Section Head / Director / EL2		\$1m	\$100k

Step 3 – Finance Business Partner (FBP) – to respond to the Project Officer providing funds availability assessment, as per [FBR R2.1](#), cost centre and the relevant financial year (where it crosses financial years).

Step 4 - Project Officer – to forward whole email trail to the Delegate

Step 5 - Delegate – as per [FBR R2.1](#), provide approval for the **total value** including the variation in the form of the following; 'I approve this commitment and confirm I am an authorised delegate under s23 (3) of the PGPA Act for this commitment proposal. The commitment approval is within the limits of my delegation as specified in the Financial Delegations.'

Step 6 - Project Officer – to forward whole email trail to the LAD lawyer

Kind regards,

s22 (she/her)

A/g Senior Lawyer - Privacy Law Section
 Corporate, Commercial and Litigation Branch

Legal and Assurance Division | Corporate Operations Group
 Australian Government, Department of Health and Aged Care
 T: 02 6289 s22 | E: s22 @health.gov.au
 Location: Sirius Building s22
 GPO Box 9848, Canberra ACT 2601, Australia

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Please note that this email and attachments may contain confidential or legally privileged information. Please consult with Legal and Assurance Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: s22 <[redacted]@ags.gov.au>
Sent: Thursday, 2 November 2023 4:27 PM
To: s22 <[redacted]@Health.gov.au>
Cc: s22 <[redacted]@health.gov.au>; s22 <[redacted]@ags.gov.au>; s22 <[redacted]@ags.gov.au>
Subject: RE: s42

Hi s22

AGS response to RFQ – LEX 46880 – s42

Thanks for your time on the phone earlier today and for the opportunity to provide a quote in this matter. Our completed quotation form is **attached** for your consideration.

As discussed, we have only set out the proposed scope of work along with our relevant assumptions for initial steps. s42

Following our initial discussions with the Department and our review of relevant documents, if we consider that scope of the work required will increase, we will provide a further estimate for the expanded scope of work.

Overall, we estimate **\$16,900 (GSTe)** for our professional fees. We anticipate that this will provide coverage for the following steps:

s42

Work on this matter will be primarily undertaken by s22 (Senior Lawyer) under the supervision of Emily Nance (Deputy Chief Solicitor), in consultation with AGS' OGC (Tara McNeilly, Senior Executive Lawyer).

Once you have had the chance to review our quote, please let me know if you have any questions or would like to discuss any aspects of this quote.

We look forward to hearing from you.

Kind regards,

s22

Senior Lawyer

Australian Government Solicitor

T 02 6253 s22

s22 <[redacted]@ags.gov.au>

Find out more about AGS at <http://www.ags.gov.au>

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From: s22 <s22@Health.gov.au>
 Sent: Tuesday, 31 October 2023 3:24 PM
 To: s22 <s22@ags.gov.au>
 Cc: s22 <s22@health.gov.au>
 Subject: [SEC=OFFICIAL] s42

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Good afternoon s22

Please find attached a Request for Quote (and accompanying background documents) for urgent advice s42

s22 and I are happy to discuss.

Kind regards,

s22 (she/her)

A/g Senior Lawyer - Privacy Law Section
 Corporate, Commercial and Litigation Branch

Legal and Assurance Division | Corporate Operations Group
 Australian Government, Department of Health and Aged Care

T: 02 6289 s22 | E: s22 <s22@health.gov.au>

Location: Sirius Building s22
 GPO Box 9848, Canberra ACT 2601, Australia

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s22

From: s22
Sent: Thursday, 9 November 2023 11:29 AM
To: s22 PLOENGES, Natasha
Cc: s22
Subject: RE: s42
 [AGSDMS-DMS.FID5018853] [SEC=OFFICIAL, ACCESS=Legal-Privilege]

Thanks s22

N FYI

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: s22 @Health.gov.au>
Sent: Thursday, 9 November 2023 11:00 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: s42
 [SEC=OFFICIAL, ACCESS=Legal-Privilege]

Hi s22

We have responded to Pfizer as advised.

See HPP corro at https://hpp.crm6.dynamics.com/main.aspx?appid=e243d638-841d-469d-aa29-766376a2c527&pagetype=entityrecord&etn=core_correspondence&id=3e1052b3-c273-ee11-8179-000d3ae1ab31 for your record.

Thanks,
 s22

From: s22 @health.gov.au>
Sent: Thursday, 9 November 2023 9:52 AM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>
Subject: FW: s42
 [SEC=OFFICIAL, ACCESS=Legal-Privilege]

Hi s22

Could you please respond to Pfizer's email of 26 October with the following. Appreciate if you can do this today and let me know when done.

Dear s47F

Thank you for your email of 26 October 2023. The Department is currently considering the matters set out in your email.

We will provide you with our substantive response as soon as we are able, ahead of the publication of the final PSD.

[signature]

Many thanks

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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s42

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s22

From: PLOENGES, Natasha
Sent: Thursday, 9 November 2023 1:46 PM
To: s22
Cc: s22
Subject: RE: Pfizer rimegepant PSD delayed publication [SEC=OFFICIAL:Sensitive]

Thanks s22

Natasha Ploenges
 (Ms/She/Her)
 Assistant Secretary
 Office of Health Technology Assessment
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | E: s22 @health.gov.au
 Location: Sirius 9.N.118
 PO Box 9848, Canberra ACT 2601, Australia

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From: s22 @health.gov.au
Sent: Thursday, 9 November 2023 10:07 AM
To: PLOENGES, Natasha s22 @health.gov.au
Cc: s22 @Health.gov.au
Subject: Pfizer rimegepant PSD delayed publication [SEC=OFFICIAL:Sensitive]

Hi N

Appreciate if you can brief Adriana on the following as discussed:

- Following internal review process, the PBAC Secretariat and Pfizer were unable to achieve an agreed negotiated outcome in relation to redaction requests for the July 2023 PSD for rimegepant (Nurtec), a medicine for acute migraine attacks.

- s42

-

- The PSD was due to be published on Friday 10 November. Pfizer will be notified today (9/11) that: *The Department is currently considering the matters set out in your email. We will provide you with our substantive response as soon as we are able, ahead of the publication of the final PSD.*

- s42

Thanks

s22 [She/Her]

Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | M s22 | E: s22 @health.gov.au

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s22

From: s22
Sent: Thursday, 9 November 2023 2:29 PM
To: s22
Cc: s22
Subject: FW: For FAS visibility: s42
 [SEC=OFFICIAL:Sensitive]

FYI

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: PLOENGES, Natasha s22 @health.gov.au>
Sent: Thursday, 9 November 2023 1:49 PM
To: PLATONA, Adriana s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: For FAS visibility: s42 [SEC=OFFICIAL:Sensitive]

Hi Adriana

- Following internal review process, the PBAC Secretariat and Pfizer were unable to achieve an agreed negotiated outcome in relation to redaction requests for the July 2023 PSD for rimegepant (Nurtec), a medicine for acute migraine attacks.
- s42
-
- The PSD was due to be published on Friday 10 November 2023. Pfizer was notified late morning (today), via the HPP that:
The Department is currently considering the matters set out in your email. We will provide you with our substantive response as soon as we are able, ahead of the publication of the final PSD.
- s42

We will keep you updated on key matters arising from this.

Thanks
 N

Natasha Ploenges
 (Ms/She/Her)
 Assistant Secretary
 Office of Health Technology Assessment

Australian Government Department of Health and Aged Care

T: 02 6289 s22 | E: s22 @health.gov.au

Location: Sirius 9.N.118

PO Box 9848, Canberra ACT 2601, Australia

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s22

From: PLOENGES, Natasha
Sent: Monday, 13 November 2023 3:33 PM
To: s47E(d)
Cc: s22
Subject: RE: MEDIA ENQUIRY July PSDs - due ASAP [SEC=OFFICIAL]

Hi

Cleared (minor revision).

For Adriana/Penny: s42

Question

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Response

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thanks

N

Natasha Ploenges
 (Ms/She/Her)
 Assistant Secretary
 Office of Health Technology Assessment
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | E: s22 @health.gov.au
 Location: Sirius 9.N.118
 PO Box 9848, Canberra ACT 2601, Australia

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From: s22 @health.gov.au>
Sent: Monday, 13 November 2023 2:53 PM
To: s47E(d) @health.gov.au>; s22 @health.gov.au>; PLOENGES, Natasha

s22 @health.gov.au>

Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22

@Health.gov.au>

Subject: RE: MEDIA ENQUIRY July PSDs - due ASAP [SEC=OFFICIAL]

N, media response for clearance, s42

Question

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Response

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the PSD in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thanks

s22 [She/Her]

Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care

T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: s47E(d) @health.gov.au>

Sent: Monday, 13 November 2023 2:36 PM

To: s22 @health.gov.au>

Cc: s22 @health.gov.au>

Subject: FW: MEDIA ENQUIRY July PSDs - due ASAP [SEC=OFFICIAL]

Importance: High

Will send this your way as well in case s22 is offline

From: s47E(d) @health.gov.au>

Sent: Monday, 13 November 2023 2:27 PM

To: s47E(d) @health.gov.au>

Cc: s47E(d) @health.gov.au>; PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>;

s22 @health.gov.au>

Subject: FW: MEDIA ENQUIRY July PSDs - due ASAP [SEC=OFFICIAL]

Importance: High

Hi s22

Media with a quick turnaround please:

Question

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Due back ASAP today.

Thanks

s22

s22 – Technology Assessment and Access Division |
Divisional Parliamentary Coordinator | Australian Government Department of Health and Aged Care

☎ (02) 6289-s22 / s22 / ✉ s47E(d) @health.gov.au

From: News <news@health.gov.au>
Sent: Monday, 13 November 2023 2:19 PM
To: s47E(d) @health.gov.au
Cc: News <news@health.gov.au>
Subject: MEDIA ENQUIRY July PSDs - due ASAP [SEC=OFFICIAL]

Hi team

Are you able to assist with the below enquiry?

Thanks

s22
Media Unit

Australian Government, Department of Health and Aged Care
T: 02 6289 s22 | s22 E: news@health.gov.au

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From: s11C @mednews.com.au>
Sent: Monday, 13 November 2023 2:17 PM
To: News <news@health.gov.au>
Subject: July PSDs

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Hi

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Cheers,

s11C

s11C

Publishing Editor

m: s11C

e: s11C [@mednews.com.au](mailto:s11C@mednews.com.au)

w: www.mednews.com.au

s11C

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s22

From: s22
Sent: Monday, 20 November 2023 10:16 AM
To: s22
Cc: s22
Subject: RE: Rimegepant PSD [SEC=OFFICIAL]

Cleared to go, thanks

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: s22 @Health.gov.au>
Sent: Monday, 20 November 2023 10:05 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: FW: Rimegepant PSD [SEC=OFFICIAL]

Hi s22

We have the following enquiry from AbbVie regarding Rimegepant PSD. We propose to respond to AbbVie with the following response s42. The response was also used for previous media enquiry (see attached for reference). Please let us know if you're happy or if there's anything we're missing.

Thanks,
 s22

Question from AbbVie

Dear PBAC Secretariat,

I am writing to enquire about the publication of the rimegepant (Nurtec ODT) public summary document. Rimegepant was evaluated at the July 2023 PBAC meeting, however the PSD does not appear to be published. Can you kindly provide an update on when this may be made available?

With kind regards,
 s47F

Response

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thanks,
 s22

From: s47F <[REDACTED]@abbvie.com>
Sent: Monday, 20 November 2023 9:42 AM
To: PBAC <PBAC@health.gov.au>
Cc: s47F <[REDACTED]@abbvie.com>
Subject: Rimegepant PSD

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Dear PBAC Secretariat,

I am writing to enquire about the publication of the rimegepant (Nurtec ODT) public summary document. Rimegepant was evaluated at the July 2023 PBAC meeting, however the PSD does not appear to be published. Can you kindly provide an update on when this may be made available?

With kind regards,

s47F

s47F

abbvie

AbbVie Pty Ltd
 Gadigal Country

Level 7, 241 O'Riordan Street
 Mascot NSW 2020

MOBILE s47F

EMAIL s47F <[REDACTED]@abbvie.com>

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s22

From: s47F @abbvie.com>
Sent: Monday, 29 January 2024 12:15 PM
To: PBAC
Cc: s47F
Subject: Follow-up Rimegepant PSD

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Outcomes Team

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Dear PBAC Secretariat,

I'm following up on the below communication re the publication of the Rimegepant (Nurtec ODT) public summary document. AbbVie notes that Rimegepant has been added to the March 2024 PBAC meeting agenda, however the PSD from July 2023 PBAC meeting does not appear to be published.

Could you please provide an update on when this may be available.

Best wishes,

s47F

s47F

abbvie

Abbvie Pty Ltd
 Level 7, 241 O'Riordan Street,
 MASCOT NSW 2020
 Gadigal Country
 Locked Bag 5029, Botany, NSW 1455
OFFICE +61 2 9035 8600
MOBILE +s47F
EMAIL s47F @abbvie.com
abbvie.com.au



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From: PBAC <PBAC@health.gov.au>
Sent: Monday, November 20, 2023 12:06 PM
To: s47F @abbvie.com>

Cc: s47F <[REDACTED]> @abbvie.com>

Subject: [EXTERNAL] RE: Rimegepant PSD [SEC=OFFICIAL]

Good afternoon s47F

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) for-rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thank you,

s22

PBAC Secretariat

From: s47F <[REDACTED]> @abbvie.com>

Sent: Monday, 20 November 2023 9:42 AM

To: PBAC <PBAC@health.gov.au>

Cc: s47F <[REDACTED]> @abbvie.com>

Subject: Rimegepant PSD

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Dear PBAC Secretariat,

I am writing to enquire about the publication of the rimegepant (Nurtec ODT) public summary document.

Rimegepant was evaluated at the July 2023 PBAC meeting, however the PSD does not appear to be published. Can you kindly provide an update on when this may be made available?

With kind regards,

s47F

s47F

abbvie

AbbVie Pty Ltd
Gadigal Country

Level 7, 241 O'Riordan Street
Mascot NSW 2020

MOBILE s47F

EMAIL s47F <[REDACTED]> @abbvie.com

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Evaluation case
Rimegepant for the treatment of acute m...

Lodgement ref
HPP005391

Evaluation case ID

EV003656

Initiated by*

Industry organisation

Response details

Department response sent by

s22

Response date

9/11/2023

10:57 AM

Response

Dear **s47F**

Thank you for your email of 26 October 2023. The Department is currently considering the matters set out in your email.

We will provide you with our substantive response as soon as we are able, ahead of the publication of the final PSD.

Thank you,
s22
PBAC Secretariat

Please click on this link to upload and attach any documents to support your correspondence.

s22

s22

From: s22
Sent: Monday, 15 January 2024 8:58 AM
To: s47E(d); s22
Subject: Re: FW: Response - MEDIA - July PSDs - follow-up - due 2:00pm Monday 15 January 2024 [SEC=OFFICIAL]

Hi s22

We will not be able to provide anything further than the previous input.

For N, s42 Would you like me to ask them for any advice about responding to this media request?

Thanks
 s22

Sent from [Workspace ONE Boxer](#)

On 15 January 2024 at 8:50:51 am AEDT, s47E(d) @health.gov.au> wrote:

Good morning s22

FYI as I don't think s22 is online yet

Thanks
 s22

From: s47E(d) @health.gov.au>
Sent: Monday, 15 January 2024 8:48 AM
To: s22 @health.gov.au>
Cc: s47E(d) @health.gov.au>; PLOENGES, Natasha s22 @health.gov.au>
Subject: FW: Response - MEDIA - July PSDs - follow-up - due 2:00pm Monday 15 January 2024 [SEC=OFFICIAL]
Importance: High

Hi s22

Media for your action by 11am if possible

Thanks
 s22

From: s47E(d) @health.gov.au>
Sent: Monday, 15 January 2024 6:39 AM
To: s47E(d) @health.gov.au>
Cc: s47E(d) @health.gov.au>
Subject: Response - MEDIA - July PSDs - follow-up - due 2:00pm Monday 15 January 2024 [SEC=OFFICIAL]
Importance: High

Hello, we have received a following up request on a media response provided back in November (see email trail).

Response due 2:00pm for FAS clearance please.

Question

I still can't see that this PSD for Nurtec ODT was ever published. Can you explain why?

The company has since resubmitted and in the interests of transparency and consistency, this needs to be published. If not, I will FOI it.

Thanks

s22

s22

TAAD Executive/PMO Section

Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
Location: Level 9, Sirius Building
PO Box 9848, Canberra ACT 2601, Australia

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From: News <news@health.gov.au>
Sent: Sunday, 14 January 2024 9:06 PM
To: s47E(d) @health.gov.au
Cc: s22 @health.gov.au; s22 @health.gov.au; News <news@health.gov.au>
Subject: FW: July PSDs - follow-up [SEC=OFFICIAL]

Hi team,

See follow-up question from journalist below – is there anything further we can provide at this time?
Deadline COB, Monday 15 January

s22

s22

Media, Communication Branch

Australian Government, Department of Health and Aged Care
T: 02 6289 7400 | M: s22 | E: news@health.gov.au

From: s11C @mednews.com.au>
Sent: Sunday, 14 January 2024 4:34 PM
To: News <news@health.gov.au>
Subject: Re: July PSDs [SEC=OFFICIAL]

Hey s22

I still can't see that this PSD for Nurtec ODT was ever published. Can you explain why?

The company has since resubmitted and in the interests of transparency and consistency, this needs to be published. If not, I will FOI it.

Cheers,

s11C

From: News <news@health.gov.au>

Sent: Monday, 13 November 2023 18:51

To: s11C <s11C@mednews.com.au>; News <news@health.gov.au>

Subject: RE: July PSDs [SEC=OFFICIAL]

Hi s11C

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thanks

s22

Media Unit

Australian Government, Department of Health and Aged Care

T: 02 6289 7400 | s22 E: news@health.gov.au

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From: s11C <s11C@mednews.com.au>

Sent: Monday, 13 November 2023 2:17 PM

To: News <news@health.gov.au>

Subject: July PSDs

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Hi

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. **As all PSDs should now have been published, can you please explain why this one is missing and provide it for me?**

Cheers,

s11C

s11C

Publishing Editor

m: s11C

e: s11C [@mednews.com.au](mailto:s11C@mednews.com.au)

w: www.mednews.com.au

s11C

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[SEC=OFFICIAL]

s22

From: s22
Sent: Thursday, 21 March 2024 10:32 AM
To: s22
Subject: RE: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Makes sense why the file name had 20240320 in it, was a bit confused. s42

just don't want to reinvent the wheel as we are just at the end of the info gathering stage and about to start drafting tracked changes version of all of the PSD process docs 😊

Cheers,

s22

My mottos:

If you do good, know for whom you are doing it, and your kindness will have its effect. (Sirach 12:1)

Without counsel plans fail, but with many advisers they succeed. (Prov 15:22)

Team work makes the dream work (1 Cor 12:25-26)

I am a supporter of the following communities/initiatives:



NATIONAL ABORIGINAL &
TORRES STRAIT ISLANDER
STAFF NETWORK



DISABILITY
& CARERS
NETWORK

From: s22 @health.gov.au>
Sent: Thursday, March 21, 2024 10:07 AM
To: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

This was new yesterday s22 I hadn't seen it before

s22 [She/Her]

Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group

Australian Government Department of Health and Aged Care

T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

This email comes to you from Ngunnawal Country

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @health.gov.au>
Sent: Thursday, March 21, 2024 9:20 AM
To: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Good morning,

Thanks for the heads up. Can I please ask you both to check [this folder](#) against all of your emails and other folders to see if I am missing any documents? I hadn't seen this amended version of the PIC in my research so far so I am not sure where it came from, but if there are more things like it I would love to have a copy please.

Cheers,
s22

My mottos:

If you do good, know for whom you are doing it, and your kindness will have its effect. (Sirach 12:1)

Without counsel plans fail, but with many advisers they succeed. (Prov 15:22)

Team work makes the dream work (1 Cor 12:25-26)

I am a supporter of the following communities/initiatives:



NATIONAL ABORIGINAL &
TORRES STRAIT ISLANDER
STAFF NETWORK



DISABILITY
& CARERS
NETWORK

From: s22 <s22@health.gov.au>
Sent: Wednesday, March 20, 2024 6:14 PM
To: s22 <s22@health.gov.au>; s22 <s22@health.gov.au>
Subject: FW: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Hi s22

s42 I'm going to suggest we don't pursue new documents for your current PSD cycle, but that we go through your proposals and run them by legals to use for the next round. I don't think we have time to digest this and get our proposed changes through legals before your next PSD deadline.

Sorry for the change in direction from our conversation earlier today.

Cheers

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 <s22@health.gov.au>

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s42

s42

From: s22 <s22@health.gov.au>
Sent: Tuesday, February 13, 2024 9:13 AM
To: s22 <s22@Health.gov.au>
Cc: s22 <s22@health.gov.au>; s22 <s22@health.gov.au>

Subject: RE: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Thanks s22

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 <s22@health.gov.au>

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 PO Box 9848, Canberra ACT 2601, Australia

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From: s22 <s22@Health.gov.au>
Sent: Tuesday, February 13, 2024 8:53 AM
To: s22 <s22@health.gov.au>
Cc: s22 <s22@health.gov.au>; s22 <s22@health.gov.au>

Subject: RE: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Thanks s22

I have actioned the below with our practice management and the work order should be in place shortly.

Kind regards,

s22 (she/her)

A/g Senior Lawyer - Privacy Law Section
Corporate, Commercial and Litigation Branch

Legal and Assurance Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care

T: 02 6289 s22 | E: s22 @health.gov.au

Location: Sirius Building 5.N.321

GPO Box 9848, Canberra ACT 2601, Australia

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From: s22 @health.gov.au>
Sent: Monday, February 12, 2024 3:43 PM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Hi s22

I approve this commitment as detailed below and confirm I am an authorised delegate under s23 (3) of the PGPA Act for this commitment proposal. The commitment approval is within the limits of my delegation as specified in the Financial Delegations.

Appreciate you undertaking next steps.
Thanks

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: s47E(d) @health.gov.au>
Sent: Monday, February 12, 2024 1:20 PM
To: s22 @health.gov.au>; s47E(d) @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>

s22 @Health.gov.au>; s22 @health.gov.au>

Subject: RE: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Hi

I have added this to the section's forecast, and this will be managed within OHTA 23-24 allocation.

s22

Health Resourcing Group
Finance Business Partner Team
Financial Business Support Branch
Ph: 6289 s22

From: s22 @health.gov.au>

Sent: Monday, February 12, 2024 12:37 PM

To: s47E(d) @health.gov.au>; s22 @health.gov.au>

Cc: s22 @health.gov.au>; s22

s22 @Health.gov.au>; s22 @health.gov.au>

Subject: RE: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Hi s22 and team

Appreciate if you can confirm funds availability for this extension to AGS.

Thanks

s22 [She/Her]

Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care

T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: s22 @Health.gov.au>

Sent: Wednesday, February 7, 2024 4:58 PM

To: s22 @health.gov.au>

Cc: s22 @health.gov.au>; s22

@health.gov.au>

Subject: LEX 46880 - further quote from AGS [SEC=OFFICIAL]

Hi s22

Thanks for your time earlier this week to discuss this matter. As discussed, I requested AGS prepare a new quote for them to complete the following work relating to this matter:

s42

AGS have quoted \$5,715.00 for this work. If you are comfortable with the quote, I would be grateful if you could complete the steps highlighted in blue and return the relevant approvals to me for action. Please note, AGS has built some additional funds into the quote as a contingency but does not expect to use all of the funds.

Step 1.a - LAD lawyer – to complete the table below and forward to the Project Officer along with the law firm quotation and Request for Quote (please include quotation in email trail, not as an attachment)

LEX ID:	46880
LAD lawyer and extension:	s22
AGS lawyer name:	s22
AGS lawyer email:	s22 @ags.gov.au
Start Date for Order of Legal Services:	(This is the date the Order is issued or where required, the date the delegate provided approval)
End date for Order for Legal Services:	30 March 2024
Total Order value:	\$5715 (excl GST)
Tied or non-tied work:	NON-TIED
Contract or Consultancy:	CONSULTANCY
Select Contract for legal services: <ul style="list-style-type: none"> • conveyancing; • development of contracts or other legal documents (and any incidental advice given relating to such work); • litigation services (including any drafting or advice connected with litigation or potential litigation); or • drafting of legislation and legislative instruments 	

Step 2 - Project Officer in line area – to complete the table below and then forward email to the relevant Finance Business Partner (FBP)

Project Officer and extension:	s22
Division:	TAAD
Cost Centre:	s47E(d)
Delegate name:	s22 (EL2)
Approve legal to action invoicing*	Choose an item. yes

Note: Approving LAD to action invoices on your behalf grants the instructing lawyer the authority to approve payment without the need to consult the line area. The instructing lawyer will act consistent with delegated PGPA s23(1) powers provided under the department's Instrument of Delegation, Schedule 1.

Note: Delegation level must be for the **total value**.

Department wide classification	Summary of power or function	Administered Contracts	Departmental Contracts
Division Head / FAS / SES B2	PGPA Act s23 (3) To approve proposals to commit relevant money	\$100m	\$10m
Branch Head / AS / SES B1		\$50m	\$1m
Section Head / Director / EL2		\$1m	\$100k

* Approving LAD to act on payments on your behalf grants the instructing lawyer the authority to approve payment without the need to consult the line area.

Step 3 - FBP – to respond to the Project Officer providing a funds availability assessment, as per [FBR R2.1](#), cost centre and the relevant financial year (where it crosses financial years)

Step 4 - Project Officer – to determine if the matter is non-urgent

Step 5 - Project Officer – to forward whole email trail to the Delegate

Step 6 - Delegate – as per [FBR R2.1](#), provide approval in an email back to the Project Officer for the **total value** including the variation using words such as:

'I approve this commitment and confirm I am an authorised delegate under s23 (3) of the PGPA Act for this commitment proposal. The commitment approval is within the limits of my delegation as specified in the Financial Delegations.'

Step 7 - Project Officer – to forward whole email trail to the LAD lawyer

Step 8 - LAD lawyer – as per [FBR R2.6](#), obtain LAD AS Endorsement for new quotes \$10,000 or more (not applicable for tied work or variations where LAD AS Endorsement has previously been obtained)

Step 9 - LAD lawyer – to forward the following in one email to s47E(d) [@health.gov.au](#) :

- Request For Quote;
- Quotation provided by the law firm;
- Funds availability assessment by the FBP;
- Delegate approval;
- LAD AS Endorsement (where applicable);
- Any other instructions.

NOTE: Commitments must be approved in SAP within two business days of approval being given in writing as required under the department's Finance Business Rules R2.1.

Kind regards,

s22 (she/her)

A/g Senior Lawyer - Privacy Law Section
Corporate, Commercial and Litigation Branch

Legal and Assurance Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care

T: 02 6289 s22 | E: s22 [@health.gov.au](#)

Location: Sirius Building 5.N.321

GPO Box 9848, Canberra ACT 2601, Australia

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Find out more about AGS at <http://www.ags.gov.au>

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OFFICIAL

From: s47E(d) <[s47E\(d\)@Health.gov.au](mailto:s47E(d)@Health.gov.au)>
Sent: Wednesday, 21 February 2024 11:22 AM
To: s22 <s22@ags.gov.au>
Cc: s47E(d) <[s47E\(d\)@Health.gov.au](mailto:s47E(d)@Health.gov.au)>; s22 <s22@Health.gov.au>
Subject: LEX 46880 - New Order for Legal Services [SEC=OFFICIAL]

CAUTION: This email originated from outside of the organisation. Do not follow guidance, click links, or open attachments unless you recognise the sender and know the content is safe.

Dear s22

Attached is the Order for Legal Services regarding the above matter.

We draw your attention to the strict terms and conditions in relation to the 80% notification and variation requirements.

Please respond with your acceptance of the Order by return email.

Should you have questions in relation to the Order please contact Legal Procurement.

Regards,

s22

Procurement Officer – Legal Policy and Practice Management
 Corporate, Commercial & Litigation Branch

Legal and Assurance Division | Corporate Operations Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | E s22 <s22@health.gov.au>
 PO Box 9848, Canberra ACT 2601, Australia

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Invoices: s47E(d) <[s47E\(d\)@concursolutions.com](mailto:s47E(d)@concursolutions.com)>

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s22

From: TURNOUR, Caroline
Sent: Monday, 8 April 2024 10:46 AM
To: s22; s47E(d)
Cc: PBAC; s22
Subject: RE: MEDIA - July PSDs due COB Monday 08/04 [SEC=OFFICIAL]

Hi
 This is cleared.
 Thanks
 Caroline

From: s22 @health.gov.au>
Sent: Friday, April 5, 2024 2:25 PM
To: s47E(d) @health.gov.au>; TURNOUR, Caroline s22 @health.gov.au>
Cc: PBAC <PBAC@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: MEDIA - July PSDs due COB Monday 08/04 [SEC=OFFICIAL]

Caroline,
 Media response for clearance.
 We will need to reiterate the same response given to the journalist on 13 November 2023 and 18 January 2024. This

s42

Happy to discuss
 s22

Question:

Can you please explain why the PSD for Nurtec ODT considered by the PBAC in July last year has still not been published?

Response:

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

s22 [She/Her]
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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 PO Box 9848, Canberra ACT 2601, Australia

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From: s47E(d) <[redacted]@health.gov.au>
Sent: Friday, April 5, 2024 12:57 PM
To: s22 <[redacted]@health.gov.au>
Cc: s47E(d) <[redacted]@health.gov.au>
Subject: FW: MEDIA - July PSDs due COB Monday 08/04 [SEC=OFFICIAL]

Good afternoon s22 [redacted] my favourite.

Please see media due **10am 08 April**.

Thank you
s22 [redacted]

From: s47E(d) <[redacted]@health.gov.au>
Sent: Friday, April 5, 2024 12:51 PM
To: s47E(d) <[redacted]@health.gov.au>
Cc: s47E(d) <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>
Subject: MEDIA - July PSDs due COB Monday 08/04 [SEC=OFFICIAL]

Hi s22 [redacted] and s22 [redacted]

For your action by 8 April, please see the media enquiry below.

We had a similar enquiry from November last year; the response is below in case you would prefer to reuse this one:

Enquiry:

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Response:

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thanks

s22 [redacted]

s22 [redacted] – Technology Assessment and Access Division |
Divisional Parliamentary Coordinator | Australian Government Department of Health and Aged Care

☎ (02) 6289-s22 [redacted] / ✉ s47E(d) <[redacted]@health.gov.au>

From: News <news@health.gov.au>
Sent: Friday, April 5, 2024 12:43 PM
To: s47E(d) <[redacted]@health.gov.au>
Cc: s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>; News <news@health.gov.au>
Subject: FW: July PSDs [alys=OFFICIAL] [SEC=OFFICIAL]

Hi team,

Please see media request below. Deadline COB Monday, 8 April.

On the 13/11/24 this journalist approached us with similar enquiry see response provided at that time below.

Enquiry:

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Response:

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thanks,
s22

s22
Media, Communication Branch

Australian Government, Department of Health and Aged Care
T: 02 6289 7400 | M: s22 | E: news@health.gov.au

From: s11C [@mednews.com.au](mailto:s11C@mednews.com.au)

Sent: Friday, April 5, 2024 12:23 PM

To: News <news@health.gov.au>

Subject: Re: July PSDs [SEC=OFFICIAL]

Hi

Can you please explain why the PSD for Nurtec ODT considered by the PBAC in July last year has still not been published?

Cheers,
s11C

Publishing Editor

m: s11C

e: s11C [@mednews.com.au](mailto:s11C@mednews.com.au)

w: www.mednews.com.au

From: News <news@health.gov.au>
Sent: Thursday, 18 January 2024 09:47
To: s11C [REDACTED] <[\[REDACTED\]@mednews.com.au](mailto:[REDACTED]@mednews.com.au)>
Cc: News <news@health.gov.au>
Subject: RE: July PSDs [SEC=OFFICIAL]

Hi s11C [REDACTED]

The Department of Health and Aged Care is still finalising several outstanding matters in respect of the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The Department will publish the final PSD on the Pharmaceutical Benefits Scheme website (www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd) as soon as possible, once these matters have been resolved.

Thanks,

s22 [REDACTED]

Media Unit, Communication Branch

Australian Government, Department of Health and Aged Care

T: 02 6289 7400 | M: s22 [REDACTED] E: news@health.gov.au

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From: s11C [REDACTED] <[\[REDACTED\]@mednews.com.au](mailto:[REDACTED]@mednews.com.au)>
Sent: Sunday, 14 January 2024 4:34 PM

To: News <news@health.gov.au>
Subject: Re: July PSDs [SEC=OFFICIAL]

Hey s22

I still can't see that this PSD for Nurtec ODT was ever published. Can you explain why? The company has since resubmitted and in the interests of transparency and consistency, this needs to be published. If not, I will FOI it.

Cheers,

s11C

From: News <news@health.gov.au>
Sent: Monday, 13 November 2023 18:51
To: s11C <s11C@mednews.com.au>; News <news@health.gov.au>
Subject: RE: July PSDs [SEC=OFFICIAL]

Hi s11C

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thanks

s22

Media Unit

Australian Government, Department of Health and Aged Care

T: 02 6289 7400 | s22 E: news@health.gov.au

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From: s11C [redacted] <s11C@mednews.com.au>

Sent: Monday, 13 November 2023 2:17 PM

To: News <news@health.gov.au>

Subject: July PSDs

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Hi

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Cheers,

s11C [redacted]

s11C [redacted]

Publishing Editor

m: s11C [redacted]

e: s11C [redacted] <s11C@mednews.com.au>

w: www.mednews.com.au

s11C [redacted]

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s22

From: s47E(d)
Sent: Monday, 13 November 2023 5:58 PM
To: News
Cc: s47E(d)
Subject: RE: MEDIA ENQUIRY July PSDs - due ASAP [SEC=OFFICIAL]

Well that was good timing – the following has been FAS cleared:

Question

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Response

The Department of Health and Aged Care is currently finalising outstanding matters in relation to the Public Summary Document (PSD) in relation to rimegepant, tablet 75 mg (Nurtec ODT®). The final PSD will be published as soon as these matters have been resolved.

Thanks very much

s22

s22 – Technology Assessment and Access Division |
 Divisional Parliamentary Coordinator | Australian Government Department of Health and Aged Care

☎ (02) 6289-s22 / ✉ s47E(d)@health.gov.au

From: s47E(d)@health.gov.au
Sent: Monday, 13 November 2023 5:53 PM
To: News <news@health.gov.au>
Cc: s47E(d)@health.gov.au
Subject: RE: MEDIA ENQUIRY July PSDs - due ASAP [SEC=OFFICIAL]

Hi team

We are just waiting for FAS clearance on this response – unfortunately she is only intermittently available this afternoon/evening, but I will forward onto you as soon as it comes back in.

Apologies for the delay.

Thanks

s22

s22 – Technology Assessment and Access Division |
 Divisional Parliamentary Coordinator | Australian Government Department of Health and Aged Care

☎ (02) 6289-s22 / ✉ s47E(d)@health.gov.au

From: News <news@health.gov.au>
Sent: Monday, 13 November 2023 2:19 PM
To: s47E(d) <[REDACTED]>@health.gov.au>
Cc: News <news@health.gov.au>
Subject: MEDIA ENQUIRY July PSDs - due ASAP [SEC=OFFICIAL]

Hi team

Are you able to assist with the below enquiry?

Thanks

s22
 Media Unit

Australian Government, Department of Health and Aged Care
 T: 02 6289 7400 | s22 E: news@health.gov.au

Unless stated otherwise, this information is provided on a background basis and should not be attributed.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s11C <[REDACTED]>@mednews.com.au>
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To: News <news@health.gov.au>
Subject: July PSDs

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Hi

I'm after the Public Summary Document for Pfizer's rimegepant (Nurtec) that was considered by the PBAC in July. As all PSDs should now have been published, can you please explain why this one is missing and provide it for me.

Cheers,
 s11C

s11C

Publishing Editor

m: s11C

e: s11C <[\[REDACTED\]@mednews.com.au](mailto:[REDACTED]@mednews.com.au)>

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s11C