[redacted]

From: TGA FOI <TGAFOI@health.gov.au>
Sent: 21 May 2021 14:52
To: [redacted]
Cc: TGA FOI
Subject: RE: FOI 2289 - Notice of Estimate of Charges [SEC=OFFICIAL]

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Dear Dr [redacted]

Thank you for your email.

In relation to your first query, whilst we understand that you were previously informed that the scope of the request may have been too voluminous, we have taken considerable extra time to reflect on the precise terms of your request, including in the light of our discussions earlier this week with the Office of the Australian Information Commissioner. Your email of 29 April 2021 also assisted in clarifying the scope of your request. Accordingly, particularly having regard to the objects of the FOI Act, and to the context of your request (including the extraordinary impact of COVID19 across the world), on this occasion, the decision-maker has decided to progress your request for documents.

In relation to your second query, I apologise for any confusion our initial correspondence may have caused - we understand now that you are seeking documents which confirm whether the TGA requested *Individual Level Patient Data* following Pfizer's application to the TGA for the provisional registration of its vaccine.

The TGA does not hold any relevant documents relating to points 1 and 2 of your FOI request, to be clear, the TGA does not hold Individual Level Patient Data in relation to this application for provisional registration.

I trust this information is of assistance. The TGA confirms payment has been received, as such we are continuing to process your request.

Kind regards
[redacted]

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

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The Department of Health 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.

[redacted]
Sent: Thursday, 20 May 2021 11:14 AM

Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-2656491

Dr [redacted]

By Email: [redacted]

Dear Dr [redacted]

FREEDOM OF INFORMATION REQUEST FOI 2289

Notice of Decision

1. I refer to your request dated 17 February 2021 under the *Freedom of Information Act 1982* (**the FOI Act**), and subsequent correspondence between you and the TGA, in which the scope of your request was clarified as being for access to the following documents:

> *"I am writing to request under the Freedom of Information Act, the following document(s) relating to the TGA's recent approval of the Pfizer vaccine for prevention of disease relating to SARS-Cov-2:*
>
> *(1) Any documents requesting access from the sponsor to the raw data (patient-level anonymised data or equivalent patient-level data) for the Pfizer phase 2/3 study referenced in the TGA's approval registered with the TGA reference COMIRNATY/BNT162b2. If this request has not been made please confirm, "no request for raw data from the sponsor was made"*
>
> *(2) Any documents confirming that a process for analysing the raw data from the sponsor (Pfizer) was undertaken, and the result of that process (e.g. meeting minutes or equivalent) including the qualifications (and names if possible) of the committee (if any) which has undertaken the review of the raw data. If no such committee review has taken place, please state "no committee review of the raw data has taken place"*
>
> *(3) Any documents relating to the designation of COMIRNATY/BNT162b2 as a category B1 for pregnancy risk based on the TGA's statement on the website "Studies in animals have not shown evidence of an increased occurrence of fetal damage." Please include the studies referenced in making the decision based on this assessment. If no animal studies were referenced, please state, "no animal studies were looked at when allocating pregnancy risk to category B1."*
>
> *[Clarification 30/03/2021]:*
>
> *"I would now be grateful if you could formalise your reply to declare that*

(1) No request for raw (patient-level) data from the sponsor [Pfizer] was made by TGA in assessing this application for provisional registration

(2) No committee review of the raw (patient-level) data from the sponsor [Pfizer] took place in assessing this application for provisional registration

(3) No animal studies were assessed when allocating pregnancy risk to category B1."

Decision Maker

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

Scope of the FOI request

3. The TGA has identified one document falling within point 3 of the scope of your request.

Background

4. On 17 February 2021, the TGA received a request from you under the FOI Act.
5. On 10 March 2021, you agreed to a seven day extension under section 15AA of the FOI Act for the processing of your FOI request.
6. On 29 March 2021, the TGA sought to clarify the scope of your request.
7. On 30 March 2021, you responded and requested:

> *"I would now be grateful if you could formalise your reply to declare that*
>
> *(1) No request for raw (patient-level) data from the sponsor [Pfizer] was made by TGA in assessing this application for provisional registration*
>
> *(2) No committee review of the raw (patient-level) data from the sponsor [Pfizer] took place in assessing this application for provisional registration*
>
> *(3) No animal studies were assessed when allocating pregnancy risk to category B1".*
>
> On 30 March 2021, you also responded and advised that you did not require specific names of individuals but that you would like their job titles to be included. You confirmed that you were not seeking duplicate documents.

8. On 1 April 2021, the Office of the Information Commissioner granted the TGA a sixty day extension under section 15AB of the FOI Act for the processing of your FOI request.
9. On 29 April 2021, the TGA contacted you to suggest that you consider revising the scope of your request to the following documents on the basis that it was likely that the scope of your request would be too voluminous to process:

Module/Evaluation Area	**Document/s**	**Description**
OVERALL	Delegate's Overview	A summary of the evaluation reports, and the reasoning behind the Delegate's proposed decision.

	Approval letter	The Approval letter is the formal correspondence to the Sponsor regarding the positive outcome of the evaluations process. The Approval letter contains; the decision to provisionally approve, duration and commencement of provisional registration, conditions of registration.
Advisory Committee on Vaccines (Independent Committee)	Background document	The advisory group for prescription medicines receives this document which includes the overview of the evaluation/Delegates concerns and requests for expert input.
	Ratified Minute	An endorse record of the advisory groups meeting, including resolutions.
Reports	Clinical overview	A report summarising the information relating to the clinical aspect of clinical studies and the Pharmacokinetics, Pharmacodynamics, Clinical efficacy, Clinical safety, Ongoing studies, Risk Benefit Assessment, recommendations.
	Toxicology overview/Non-clinical review	A report summarising the nonclinical data submitted, evaluation of nonclinical pharmacology and toxicology data submitted. Further, assessment and recommendations for sections of the Product Information that contain nonclinical data, including Use in Pregnancy and pregnancy categorisation.
	Risk Management Plan	The RMP provides information on a medicine's safety profile, describes the activities of the marketing authorisation holder to further characterise the safety profile during post-marketing (pharmacovigilance activities), and explains the measures that are taken in order to prevent or minimise the medicine's risks in patients (risk minimisation measures).

10. On 29 April 2021, you responded confirming that you were not willing to agree to change the scope of your request and stated:

"I would like to try to help by making clear the following:

(1) My request was for any documentary evidence that the TGA requested the patient-level data from Pfizer. This cannot possibly be a voluminous request by any stretch of the imagination. Even if all 40 members of the advisory committee sent a request to Pfizer

individually (which they clearly would not have done) this would have only generated 40 emails/letters. Because you are claiming that this is a voluminous request I am requesting that you show one example of a request from the TGA to Pfizer for raw patient-level anonymised data. Alternatively please send a link to the actual raw data from Pfizer (this is NOT the submission summary in the AusPAR). The dataset should contain approx. 44,000 records.

(2) If the TGA does not have access to the 44,000 record data set from Pfizer, please state in your response "The TGA does not have access to the full patient record dataset from the Pfizer vaccine study" in your response to Part 1 of the original request.

(3) If you do not understand the scope of my request, despite my previous clarifications it is incumbent on you within the confines of the Act to clarify the very narrow scope of questions I am asking.

(4) My request was not for summary documents which do not contain references to the raw data. The whole point of the request is to confirm that the ACV did not request or verify or perform a forensic analysis of the patient-level data from Pfizer, but merely took Pfizer's word that the study data submitted was a true representation of 44,000 clinical records. In order to establish whether this was the case all you would have to do is request whether any member of the ACV or associated groups requested the patient-level data from Pfizer for independent verification. As there are only 10 members of this group this should be very easy to do. You are welcome to forward my original text request to them if this helps. If only 1 member of the group requested the data, you should be able to provide it and answer the FOI request easily.

(5) In regards to animal studies (part 3 of the request) I am aware that there are no published animal studies relating to teratogenicity of Comirnaty in pregnancy. The AusPAR only references one study which is not described other than being mentioned that "a study was conducted [by Pfizer]" without any reference (pubmed link, researchgate link, DOI etc) for which this study can be independently assessed. It is therefore not possible that my request in part 3 can be voluminous."

11. On 19 May 2021, you were advised that the cost of processing your request amounted to $595.58 and you were asked to pay a deposit of $148.90. Following the above clarification, you were advised that the TGA does not hold any relevant documents relating to points 1 and 2 of your request and holds 1 document in relation to point 3 of your request. You were also advised at this time that the TGA had commenced third party consultation in relation to that document.

12. On 20 May 2021, you responded and advised that you had paid the deposit of $148.90. On the same date, the TGA received your deposit for the processing of your request. You also asked

"I need to make two requests on the back of this response:

(1) I would like to clarify that your office has claimed to the Information commissioner that my request was voluminous but the attached letter is clearly stating that you are providing only one document. It is very important at this point, given that the deadline is in a few days, that you clarify that you stated that the reason for you to request a delay from the information commissioner was the voluminous nature of the document request.

(2) *In your response to question (1) of the request you have claimed that the raw patient data was sent with the submission. Please can you confirm that the TGA possess this data (i.e. patient-level anonymised records of 44,000 patients), in*

what format it was received (e.g. electronic database or clinical record forms) and whether I will need to make a separate FOI request to access this part of the submission."

13. On 21 May 2021, the TGA responded to your email. In relation to your first query, the TGA explained:

"…whilst you were previously informed that the scope of the request may have been too voluminous, we have taken considerable extra time to reflect on the precise terms of your request. Your email of 29 April 2021 also assisted in clarifying and narrowing the scope of your request. Accordingly, particularly having regard to the objects of the FOI Act, and to the context of your request (including the extraordinary impact of COVID19 across the world), on this occasion, the decision-maker decided to progress your request for documents. Notwithstanding that processing such a request may ordinarily have been considered too voluminous, given the size of the one document (1,145 pages) falling within the scope of your request. In relation to your second query, the TGA now understands that you are seeking documents that confirm whether the TGA requested Individual Level Patient Data following the sponsor's application to the TGA for the provisional registration of its vaccine. The TGA confirms that we do not hold Individual Level Patient Data in relation to this application for provisional registration."

Decision

14. My decision in relation to the document falling within the scope of your FOI request is to release one document in part. The document is an animal toxicity study report that was provided to the TGA as part of the Pfizer's COVID-19 vaccine provisional registration application.

15. At the outset, please note that I have decided to release some information that is not otherwise publicly available in the report, including:

- the table of contents, tables and appendices;
- quality assurance and compliance statements
- the abstract; and
- part of the introduction and the conclusion.

16. Otherwise, I have decided that the remainder of the information in the document is exempt.

17. My decision not to provide you with full access to the document is based on the application of section 47 of the FOI Act. The reasons for the application of this exemption provision to the document are set out in detail below. Irrelevant information has also been removed under section 22 of the FOI Act.

18. The preliminary estimate of charges associated with processing this FOI request was $595.58. This amount includes the first five hours of decision making at no cost. In accordance with the *Freedom of Information (Charges) Regulations 2019* (the Charges Regulations). I have calculated the actual charges that can be imposed for processing your request are $263.75.

19. Therefore, as you have already paid the deposit in the amount of **$148.90**, you are required to pay the balance of $114.85 before the documents can be released to you.

Material Considered in Decision-Making

20. In coming to my decision I had regard to the following:

- the correspondence between the TGA and yourself;
- the documents falling within the scope of the FOI request;
- all relevant papers in the TGA FOI processing file;
- the provisions of the FOI Act, in particular sections 22 and 47 of the FOI Act;
- Parts 5 and 6 of the guidelines published by the Australian Information Commissioner under section 93A of the FOI Act which can be found at https://www.oaic.gov.au/freedom-of-information/foi-guidelines;
- consultation with the third party whose document is involved.

Payment

21. Payment can be made via one of the following options:

- **Credit card payment**:
  Complete the *attached* form (also available via the following link):
  www.tga.gov.au/form/credit-card-payment-authorisation.
- **Electronic Funds Transfer:**
  Payment can be made in the form of electronic funds transfer to the following account:
  Bank: Commonwealth Bank of Australia
  Account Name: Therapeutic Goods Administration
  BSB: 062909
  Account: 10215498
- **Cheque:**
  Please make cheques payable to Therapeutic Goods Administration, and post to
  FOI Coordinator
  Therapeutic Goods Administration
  PO Box 100
  WODEN ACT 2606

Please include reference to FOI 2289 in all forms of payment.

22. **IMPORTANT**: Once payment has been made, please notify the FOI Team via the following email address: TGA.FOI@tga.gov.au.

23. Failure to notify the FOI Team of payment will result in delays to the processing of your FOI request.

Reasons for Decision

24. One document has been identified as relevant to your request. A schedule listing the document identified as falling within the scope of your request is at **Attachment A** and refers to the provisions which are claimed to apply to the document.

25. As noted above, I have decided to delete some irrelevant information under section 22 and exempt some information under section 47 of the FOI Act. A copy of the relevant provisions of the FOI Act is at **Attachment B**.

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

26. The effect of subsection 22(1) of the FOI Act is that where the granting of access to a document would disclose information that is not within the scope of the request and it is possible to provide a copy with information deleted, the agency can do so unless it is evident that the applicant does not wish to be provided access to such a copy. A copy of subsection 22(1) is at **Attachment B**.

27. The relevant documents contain information that does not fall within the scope of your FOI request. Specifically, the document contains contain personal information such as individuals' names, phone numbers and email addresses, which you confirmed are not part of your request. You will note that individuals' job titles have not been redacted.

28. I consider that to provide you with full access to the document would disclose irrelevant information that does not fall within the scope of your FOI request. Accordingly, I have decided that the irrelevant information will be deleted under subsection 22(1) of the FOI Act and a copy of the documents, with the irrelevant information deleted, will be provided to you.

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

29. Under section 47 of the FOI Act, a document is an exempt document if it contains a trade secret (paragraph 47(1)(a)) or contains information that has commercial value that could reasonably be expected to be destroyed or diminished if it were disclosed (paragraph 47(1)(b)). I consider any information that has a commercial value would also include any information that is a trade secret. Therefore, I have only considered whether the information in question has a commercial value. A copy of paragraph 47(1)(b) is at **Attachment B**.

30. As set out above, I have decided to release some information that is not otherwise publicly available in the report, including:

    - the table of contents, tables and appendices;
    - quality assurance and compliance statements
    - the abstract; and
    - part of the introduction and the conclusion.

31. Otherwise, I have decided that the remainder of the information is exempt for the reasons set out below.

32. Paragraph 5.205 of the FOI Guidelines states that the following factors may assist in deciding in a particular case whether information has a commercial value:

    - whether the information is known only to the agency or person for whom it has value or, if it is known to others, to what extent that detracts from its intrinsic commercial value;
    - whether the information confers a competitive advantage on the agency or person to whom it relates – for example, it if lowers the cost of production or allows access to markets not available to competitors;
    - whether a genuine 'arm's-length' buyer would be prepared to pay to obtain that information;
    - whether the information is still current or out of date (out of date information may no longer have any value); and
    - whether disclosing the information would reduce the value of a business operation or commercial activity – reflected, perhaps, in a lower share price.

33. Having regard to the submissions of the third party (Pfizer) and taking into account the FOI Guidelines, I am satisfied that the following non-public information contained in the document is commercially valuable information, the value of which would be diminished or destroyed if released:

- name of third part party testing facility
- specific processes, materials, methods and designs used to carry out the study
- comprehensive and detailed data relating to the statistical analysis and results

Whether the information is known only to the agency or person for whom it has value or, if it is known to others, to what extent that detracts from its intrinsic commercial value

34. As mentioned above, the document is an animal toxicity study report that was provided to the TGA as part of Pfizer's provisional registration application for its COVID-19 vaccine, COMIRNATY. I am satisfied that Pfizer has actively taken steps to ensure the information contained in this document is not disclosed to the general public or its competitors, rather it has only been submitted (in confidence) to regulatory bodies for the purpose of evaluating the product for supply in relevant jurisdictions.

35. The TGA's technical experts have indicated that only basic information about this study (namely, the study number and the nature of the study as a reproductive toxicity study) is in the public domain. As far as I am aware, the remainder of the information within the document is not otherwise publicly available in Australia or other jurisdictions.

36. In light of the above, I am satisfied that the relevant information possesses an intrinsic commercial value that has not been diminished by disclosure to others.

Whether the information confers a competitive advantage on the agency or person to whom it relates – for example, it if lowers the cost of production or allows access to markets not available to competitors

37. In considering whether this information confers a competitive advantage on the sponsor, I have considered the fact that Pfizer's vaccine is the first (and currently the only) provisionally approved mRNA vaccine in Australia. Pfizer currently enjoys a certain market share noting its successful provisional registration application.

38. I am aware that there are a great number of other companies around the world attempting to create a viable COVID19 mRNA vaccine with various levels of success. I am satisfied that the release of this information is likely to provide competitors with insights into components of a successful application for the registration of an mRNA vaccine in Australia, and I am of the view that a competitor could use the information to replicate this study without expensing the equivalent financial costs incurred by the third party.

Whether a genuine 'arm's-length' buyer would be prepared to pay to obtain that information

39. For the reasons set out above, I am satisfied that a competitor would be prepared to pay to obtain this information to assist it in submitting its own application for a similar product.

40. Pfizer has invested substantial resources into the design and testing of its vaccine and this information would be of value to a competitor seeking to supply a similar vaccine, particularly an mRNA vaccine. I consider that the release of this information could enable a competitor to capitalise on, or replicate, the sponsor's trial results in order to obtain access to the market and/or gain a competitive advantage. On this basis, I am satisfied that a third party would be prepared to pay to obtain this information.

Whether the information is still current or out of date (out of date information may no longer have any value)

41. I am of the view that the information is current and retains its value. I note that Pfizer's vaccine has only been provisionally approved for a matter of months, and that there are a great number of competitors around the globe who are in the process of trying to develop vaccines in relation to COVID-19. Additionally, I am aware that COMIRNATY remains the only mRNA vaccine available on the Australian market.

Whether disclosing the information would reduce the value of a business operation or commercial activity – reflected, perhaps, in a lower share price.

42. The affected third party did not address this matter in its submission. I am not in a position to speculate on the effect that release may have on the value of Pfizer's business, including its share price.

Summary

43. On balance, I am of the view that the above information has a commercial value that could reasonably be expected to be destroyed or diminished if it were disclosed.

44. Accordingly, parts of the document (as identified in the schedule at **Attachment A**) are exempt under section 47 of the FOI Act and therefore have been deleted from the document.

Release of Documents

45. Once you have paid the balance of the charges, being **$114.85**, the document can be released to you.

Review and Complaint Rights

46. If you are not satisfied with this decision, you can either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/reviews-and-complaints/

47. If you have any queries regarding this matter, please contact Rebecca Wheeler on (02) 6289 2147 or the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Elizabeth Santolin
Director
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
25 May 2021

FOI Request 2289

"Any documents relating to the designation of COMIRNATY/BNT162b2 as a category B1 for pregnancy risk based on the TGA's statement on the website "Studies in animals have not shown evidence of an increased occurrence of fetal damage." Please include the studies referenced in making the decision based on this assessment. If no animal studies were referenced, please state, "no animal studies were looked at when allocating pregnancy risk to category B1."

Schedule of Relevant Documents

Doc. No.	Date	Description	Pages	Decision	Relevant Sections of the FOI Act
1	22/12/2020	Test Facility Study No. 20256434 Final Report	**Redactions to the following pages:** 1, 8 – 10 and 13 **Exempt pages:** 14 – 37, 39 – 1145 **Release in full the following pages:** 2 – 7, 11 – 12 and 38	Irrelevant material redacted (personal information) Clinical trial data redacted from the document as commercially valuable	22 47

Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-2647292

Dr [redacted]

By email: [redacted]

Dear Dr [redacted]

FREEDOM OF INFORMATION REQUEST FOI 2289
Estimate of Charges

I refer to your request dated 17 February 2021 under the *Freedom of Information Act 1982* (the FOI Act) and subsequent correspondence between you and the TGA in which the scope of your request was clarified as being for access to the following documents:

> *"I am writing to request under the Freedom of Information Act, the following document(s) relating to the TGA's recent approval of the Pfizer vaccine for prevention of disease relating to SARS-Cov-2:*
>
> *(1) Any documents requesting access from the sponsor to the raw data (patient-level anonymised data or equivalent patient-level data) for the Pfizer phase 2/3 study referenced in the TGA's approval registered with the TGA reference COMIRNATY/BNT162b2. If this request has **not** been made please confirm "no request for raw data from the sponsor was made"*
>
> *(2) Any documents confirming that a process for analysing the raw data from the sponsor (Pfizer) was undertaken, and the result of that process (e.g. meeting minutes or equivalent) including the qualifications (and names if possible) of the committee (if any) which has undertaken the review of the raw data. If no such committee review has taken place, please state "no committee review of the raw data has taken place"*
>
> *(3) Any documents relating to the designation of COMIRNATY/BNT162b2 as a category B1 for pregnancy risk based on the TGA's statement on the website "Studies in animals have not shown evidence of an increased occurrence of fetal damage.". Please include the studies referenced in making the decision based on this assessment. If no animal studies were referenced please state "no animal studies were looked at when allocating pregnancy risk to category B1."*
>
> *[Clarification 30/03/2021]:*
>
> *"I would now be grateful if you could formalise your reply to declare that*
>
> *(1) No request for raw (patient-level) data from the sponsor [Pfizer] was made by TGA in assessing this application for provisional registration*
>
> *(2) No committee review of the raw (patient-level) data from the sponsor [Pfizer] took place in assessing this application for provisional registration*
>
> *(3) No animal studies were assessed when allocating pregnancy risk to category B1."*

At the outset, I note that in your clarification email of 30 March 2021, you requested that the TGA make declarations as to whether certain requests were made by the TGA to Pfizer Australia Pty Ltd regarding its application for provisional registration of its COVID19 vaccine. Sections 11 and 11A of the FOI Act provide that a person has a legally enforceable right to request access to *documents* held by the relevant agency. Additionally, section 15 of the FOI Act provides that requests under the FOI Act must specify the relevant *documents* requested. As you would appreciate, the FOI Act does not require nor provide a mechanism for decision makers to make declarations or statements as part of a decision letter. Accordingly, and consistent with the FOI Act, I have interpreted your scope as a request for documents held by the TGA within the scope of your request.

Please be advised that the TGA does not hold any relevant documents relating to points 1 and 2 of your clarified scope. As you may be aware, for a therapeutic product such as a vaccine to be registered on the Australian Register of Therapeutic Goods (ARTG) by the TGA to treat COVID-19, a sponsor (usually a pharmaceutical company) is required to submit a comprehensive developmental dossier application for the medicine. This dossier usually consists of clinical study data, non-clinical/toxicology studies, and other information/reports. Further information about dossiers can be found at https://www.tga.gov.au/dossier-documents-matrix-module-2-5.

Once accepted by the TGA, a formal evaluation of the application is undertaken in multiple stages by technical experts. To ensure that decisions are robust and well made, the TGA employs delegates who are Medical Officers in various fields of expertise. Input into regulatory decisions is also informed by toxicologists, scientists, pharmacists and other highly qualified and experienced staff. The TGA also refers matters to independent experts via a number of advisory committees, which provides the TGA with access to Australia's most eminent and respected clinical and scientific experts.

In relation to point 1 of your request, clinical trial data (i.e. raw data) is submitted by the sponsor as per the TGA's existing and regular dossier requirements – the TGA does not request this, rather it must be submitted in order for the TGA to carry out its assessment for safety, quality and efficacy of the goods.

Similarly, in relation to point 2 of your request, the Advisory Committee on Vaccines (ACV) does not generally request raw data directly from the sponsor of a medicine. In most circumstances, ACV members are provided with a range of documents, which provide background information on the data submitted by the sponsor as well as an overview of the TGA's evaluation of the relevant dossier.

I understand that the TGA's FOI team contacted you on 29 April 2021, with a suggested revised scope to assist you in obtaining documents that would be of assistance to you, noting your queries above. Those documents included reports that outlined the studies that were submitted to the TGA. I also note the revised scope included the briefing document that was provided to members of the ACV in preparation for the meeting to discuss the Pfizer's provisional registration application for its COVID-19 vaccine. I understand that you declined the offer to revise your scope to these documents.

The TGA has identified 1 document falling within the scope of point 3 of your request, charges relating to the processing of this document are outlined below.

Charges

Under the *Freedom of Information (Charges) Regulations 2019* (the Regulations), a charge can be imposed in respect of a request for access to documents under the FOI Act. The charge is for the search and retrieval of documents, decision-making and provision of access (for example, copying and postage).

I am an authorised decision maker under section 23 of the FOI Act and I have decided that you are liable to pay a charge in respect of the processing of your request for access.

A search and retrieval of documents relevant to your request has been undertaken and a preliminary estimate of charges has been calculated. It is set out in the table below.

1.	Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	4.25 hours @ $15.00 per hour	$63.75
2.	Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	31.59 hours @ $20.00 per hour Less first 5 hours which are free	$531.83
3.	Postage charges		$0.00
TOTAL			$595.58
Deposit required			$148.90

Under the Regulations where a charge is imposed and exceeds $100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is $595.58, I have decided you are required to pay a deposit of 25 percent, being $148.90. Details of payment methods are outlined below.

Under subsection 29(1) of the FOI Act, I am required to notify you that you have 30 calendar days from receipt of this notice to do one of the following:

- pay the charge, being the deposit outlined above, and notify the FOI Team via the email below; or
- notify the TGA that you wish to contend that:
  - the charge has been wrongly assessed, giving reasons; or
  - the charge should be reduced or not imposed (for instance, where payment of the charge would cause you financial hardship or where you believe access to documents is in the general public interest), with reasons; or
- notify the TGA that you withdraw your request.

Please note, should you seek a reduction or waiver of charges on the grounds of financial hardship it would assist the decision maker considering your request if you provide suitable evidence of financial hardship (for example, by providing evidence of receipt of a pension or income support payment; or provide evidence of income, debts or assets). This is consistent with the FOI Guidelines https://www.oaic.gov.au/freedom-of-information/foi-guidelines/part-4-charges-for-providing-access. Evidence should be provided at the time of seeking waiver or reduction.

If you fail to notify the TGA within 30 days about what you propose to do, the FOI Act provides under subsection 29(2) that you are taken to have withdrawn your request.

Timeframes
The time limit for processing your request is suspended, in accordance with section 31 of the FOI Act, from the date you receive this notice and resumes on the day you pay the charge or deposit (including any reduced charge or deposit), or the day on which the TGA makes a decision not to impose a charge.

Once your FOI request has been processed, the TGA will determine the actual charge you must pay before the documents can be provided to you. In this case, we do not anticipate that the actual charges will be more than the estimate of charges.

If you agree to pay the charge, you are accepting liability for settlement of the debt upon completion of processing the FOI request. Once your FOI request has been processed, the outstanding amount of the charge becomes a debt to the Commonwealth. The TGA is obliged to pursue recovery of the debt in accordance with the *Public Governance, Performance and Accountability Act 2013.*

Payment
If you accept liability for the estimated charge for your request, payment can be made via one of the following options:

- **Credit card payment**:
  Complete the credit card payment authorisation form provided with this correspondence
- **Electronic Funds Transfer:**
  Payment can be made in the form of electronic funds transfer to the following account:

  Bank: Commonwealth Bank of Australia
  Account Name: Therapeutic Goods Administration
  BSB: 062909
  Account: 10215498
- **Cheque:**
  Please make cheques payable to Therapeutic Goods Administration, and post to

  FOI Coordinator
  Therapeutic Goods Administration
  PO Box 100
  WODEN ACT 2606

Please include reference to FOI 2289 in all forms of payment.

IMPORTANT: Once payment has been made, please notify the FOI Team via the following email address: TGA.FOI@tga.gov.au.

Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation
As your request relates to documents that include information about a person or their business or professional affairs or about the business, commercial or financial affairs of an organisation or undertaking, pursuant to section 27 and 27A of the FOI Act, the TGA is required to provide that person or organisation the opportunity to make submissions if it appears that they may wish to argue any document is exempt from release.

Accordingly, as the TGA has commenced third party consultation, the statutory time limit for processing this FOI request has already been extended by 30 days under subsection 15(6) of the FOI Act to allow this process to be undertaken.

If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Elizabeth Santolin
Director
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
19 May 2021

Australian Government
Office of the Australian Information Commissioner

Our reference: RQ21/00761
Agency reference: FOI-2289

Mr [redacted]

Sent by email: [redacted]

Extension of time under s 15AB

Dear Mr [redacted]

On 25 March 2021, the Department of Health (the Department) applied for further time to make a decision on your FOI request of 17 February 2021 under the *Freedom of Information Act 1982* (Cth) (the FOI Act).

This application was made on the basis that the processing period is insufficient to deal adequately with your request, because it is complex and voluminous.

The Department previously obtained your agreement under s 15AA of the FOI Act for a 7-day extension of time to 26 March 2021 (OAIC reference: RQ21/00578).

Contact with you

On 29 March 2021, the OAIC wrote to you to seek your view on the Department's application. On 30 March 2021, you responded to our inquiries and provided comments that I have taken into consideration, including that:

> I note that the TGA FOI team have sent two emails to me yesterday asking for clarification, but these were beyond the original deadline time and beyond the revised deadline time. I have provided this clarification to them today.
>
> The request was extremely simple and clear. It does not require the generation of large datasets. It simply requires that there was evidence that the TGA looked at the original patient-level data from Pfizer in making the assessment for approval as well as providing the references to the studies used to support the pregnancy classification (of which they claim only one).
>
> It is absolutely clear that the TGA are treating the FOI legislation with contempt. In the absence of any further clarification from the agency as to *specifically* what documents they require *6 months* to glean I am unable to agree to this request.
>
> I sincerely hope that you will use your authority and responsibility to the Australian public to impose the regulations set in legislation to request transparency from the TGA.

Decision

As a delegate of the Information Commissioner, I am authorised to make decisions on applications for extensions of time under s 15AB of the FOI Act.

Although the Department has requested an extension of time of 180 days, based on the information currently before the OAIC, I have decided to grant the Department an extension of time of 60 days under s 15AB(2) **to 25 May 2021** as I am satisfied that an extension of 60 days is appropriate and justified in this circumstance because the request is complex and voluminous. My reasons and considerations follow.

In its application for an extension of time to process your FOI request, the Department advised:

- The request requires the line areas to assess the full dossiers for either individual or multiple COVID-19 vaccines which have been submitted to the TGA for assessment and consideration of safety, quality and efficacy;
- There is a substantial volume of documents provided for consideration of any application to register a vaccine with the TGA (tens of thousands of pages); and
- The relevant line areas are also the area responsible for assessing and monitoring COVID-19 vaccines (including dealing with vaccine approvals, regulating or assessing manufacturers, lab testing and assessing post market safety signals). As such, it is difficult at this time to access the specialist staff required to assist with assessing the documents due to their respective roles in assessing and monitoring COVID-19 vaccines.

I have also taken into consideration the critical public health work currently being undertaken by the Department, however I am also mindful that to grant an extension of time for an additional 180 days would impact on your right to access information which is of current public interest.

While I note your objection to this extension of time, based on the information currently before the OAIC, I am satisfied that granting a variation of 60 days rather than 180 days weighs up the above competing factors and is consistent with the objects of the FOI Act, to facilitate and promote public access to information promptly and at the lowest reasonable cost.

If the Department does not make a decision by 25 May 2021 you may wish to seek Information Commissioner review of the Department's deemed refusal of your request here. Further information on applying for IC review is available on the OAIC website.

Contact

If you have any questions, please contact me via email FOIDR@oaic.gov.au In all correspondence please include the relevant OAIC reference at the top of this page.

Yours sincerely

[redacted]
Director Investigations and Compliance
Freedom of Information

1 April 2021

[redacted]

FINAL REPORT

Test Facility Study No. 20256434

Sponsor Reference No. RN9391R58

A Combined Fertility and Developmental Study (Including Teratogenicity and Postnatal Investigations) of BNT162b1, BNT162b2 and BNT162b3 by Intramuscular Administration in the Wistar Rat

GLP Study

SPONSOR:
BioNtech SE
12 An der Goldgrube
Mainz, 55131
Germany

TEST FACILITY:

[redacted]

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QUALITY ASSURANCE STATEMENT

This study has been audited by Quality Assurance in accordance with the applicable Good Laboratory Practice regulations. Reports were submitted in accordance with Standard Operating Procedures as follows:

QA INSPECTION DATES

Date(s) of Audit	Phase(s) Audited	Dates Findings Submitted to: Study Director	Dates Findings Submitted to: Study Director Management
29-Jun-2020 – 30-Jun-2020	Final Study Plan	30-Jun-2020	30-Jun-2020
23-Jul-2020	Study Plan Amendment 01	23-Jul-2020	23-Jul-2020
02-Oct-2020	Study Plan Amendment 02	02-Oct-2020	02-Oct-2020
14-Sep-2020	Physical development	14-Sep-2020	14-Sep-2020
23-Nov-2020 – 04-Dec-2020	Report Tables	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Report – Materials and Methods	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Data Review – Formulations	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Data Review – Technical Operations	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Data Review – Clinical Pathology	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Data Review – Necropsy	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Report	04-Dec-2020	04-Dec-2020
07-Dec-2020 - 10-Dec-2020	Report - Results	10-Dec-2020	10-Dec-2020

In addition to the above-mentioned audits, process-based and routine facility inspections were also conducted during the course of this study. Inspection findings, if any, specific to this study were reported by Quality Assurance to the Study Director and Management and listed as a Phase Audit on this Quality Assurance Statement.

The Final Report has been reviewed to assure that it accurately describes the materials and methods, and that the reported results accurately reflect the raw data.

[redacted]

Quality Assurance Auditor

GLP COMPLIANCE STATEMENT AND REPORT APPROVAL

The study was performed in accordance with OECD Principles of Good Laboratory Practice as required in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004, Bonnes Pratiques de Laboratoire, Ministère de l'Emploi et de la Solidarité Française, No. 2000/5bis, arrêté du 14/03/2000.

OECD Principles of Good Laboratory Practice are accepted by Regulatory Authorities throughout the European Union, United States of America (FDA and EPA), and Japan (MHLW, MAFF, and METI) and other countries that are signatories to the OECD Mutual Acceptance of Data Agreement.

Exceptions from the above regulations are listed below.

- Antibody analysis (Appendix 26) was not conducted in compliance with GLP but in accordance with the Good Clinical Laboratory Practice (GCLP). This Test site was selected by the Sponsor because it has the most appropriate experience concerning the measurement of neutralizing antibody titres against the SARS-CoV-2 live virus by Microneutralization CPE-based method. The delegated phase for antibody analysis was fit for purpose, performed in adherence to the facilities SOPs and working instructions, by a research facility with proper expertise, and adequate history and by individuals specially trained in this technique (according to VisMederi management of personnel procedure). This exception did not adversely affect the outcome or interpretation of this study because the methods included appropriate controls to provide reliable data and analyses according to data integrity principles and local QA Report review will ensure compliance to internal procedures.

Study Director

1. RESPONSIBLE PERSONNEL

Role/Phase	[redacted]	Name	Contact Information
Study Director		[redacted] PhD	[redacted]
Test Facility Management		[redacted] General Director	
Test Facility QAU		[redacted] MSc, Chemical Engineer	

[redacted]

2. ABSTRACT

The objective of this study was to assess the potential effects of BNT162b1, BNT162b2 and BNT162b3, vaccine development candidates to prevent Covid-19, and the concomitant immune response, on fertility and pre and postnatal development in the female Wistar (CRL:WI[Han]) rat.

BNT162b1, BNT162b2 and BNT162b3 were administered intramuscularly (IM) to F0 female Wistar rats 21 and 14 days before the start of mating (M-21 and M-14, respectively) and then on Gestation Day (GD) 9 and GD20, for a total of 4 dose days. A separate control group was administered saline by the same route and regimen. Each dose group consisted of 44 F0 females, 22 rats assigned to the caesarean subgroup, and 22 rats assigned to the littering subgroup. Each dose consisted of 30 µg mRNA /dosing day (0.06 mL/dose) IM injection in alternating quadriceps muscles.

Following completion of a mating phase with untreated males, 22 rats per group (nominally) underwent caesarean section on GD21 and were submitted to routine embryo-fetal development evaluations (caesarean subgroup). The remaining 22 rats per group (nominally) were allowed to litter and development of the offspring was observed up to weaning on Postnatal Day (PND) 21 (littering subgroup).

The following parameters and end points were evaluated in all F0 animals: Survival, clinical signs, body weights, body weight gains, food consumption, estrous cycles, mating performance, fertility and macroscopic observations. F0 females assigned to the caesarean subgroup were further examined for ovarian and uterine contents, gravid uterine weights and fetuses were evaluated for viability, sex, body weights, and external, visceral, and skeletal morphology. F0 females assigned to the littering subgroup were allowed to deliver naturally, and were further assessed for parturition, lactation, and maternal behavior, and were monitored to the day of euthanasia on Lactation Day (LD) 21. F1 offspring were assessed for survival, clinical signs, body weights, physical development (pinna unfolding and eye opening), preweaning auditory and visual function tests to screen for normal neurodevelopment, and macroscopic observations.

Blood samples were collected before administration of the first dose (baseline) and on the first day of cohabitation for each F0 female (both subgroups), on GD21 (caesarean subgroup), and on LD21 (littering subgroup females). Blood samples were also collected on GD21 from viable fetuses in each available litter (caesarean subgroup) and on PND21 from pups from each available litter (littering subgroup). Blood samples were evaluated for neutralizing antibody titres against SARS-CoV-2 live virus.

There were no deaths throughout the study related to any of the 3 vaccine candidates.

Intramuscular administration of BNT162b1, BNT162b2 and BNT162b3, before and during gestation to female Wistar rats resulted in non-adverse clinical signs and macroscopic findings localized to the injection site as well as transient, non-adverse body weight and food consumption effects after each dose administration. These maternal findings are all consistent with administration of a vaccine and an inflammatory/immune response.

There were no effects on estrous cycles, pre-coital interval, mating, fertility and pregnancy index, or on any ovarian, uterine, or litter parameters, including F1 pre and postnatal survival, growth, external, visceral, and skeletal morphology, or effects on pre-weaning physical and functional development of the F1 pups related to any of the 3 vaccine candidates.

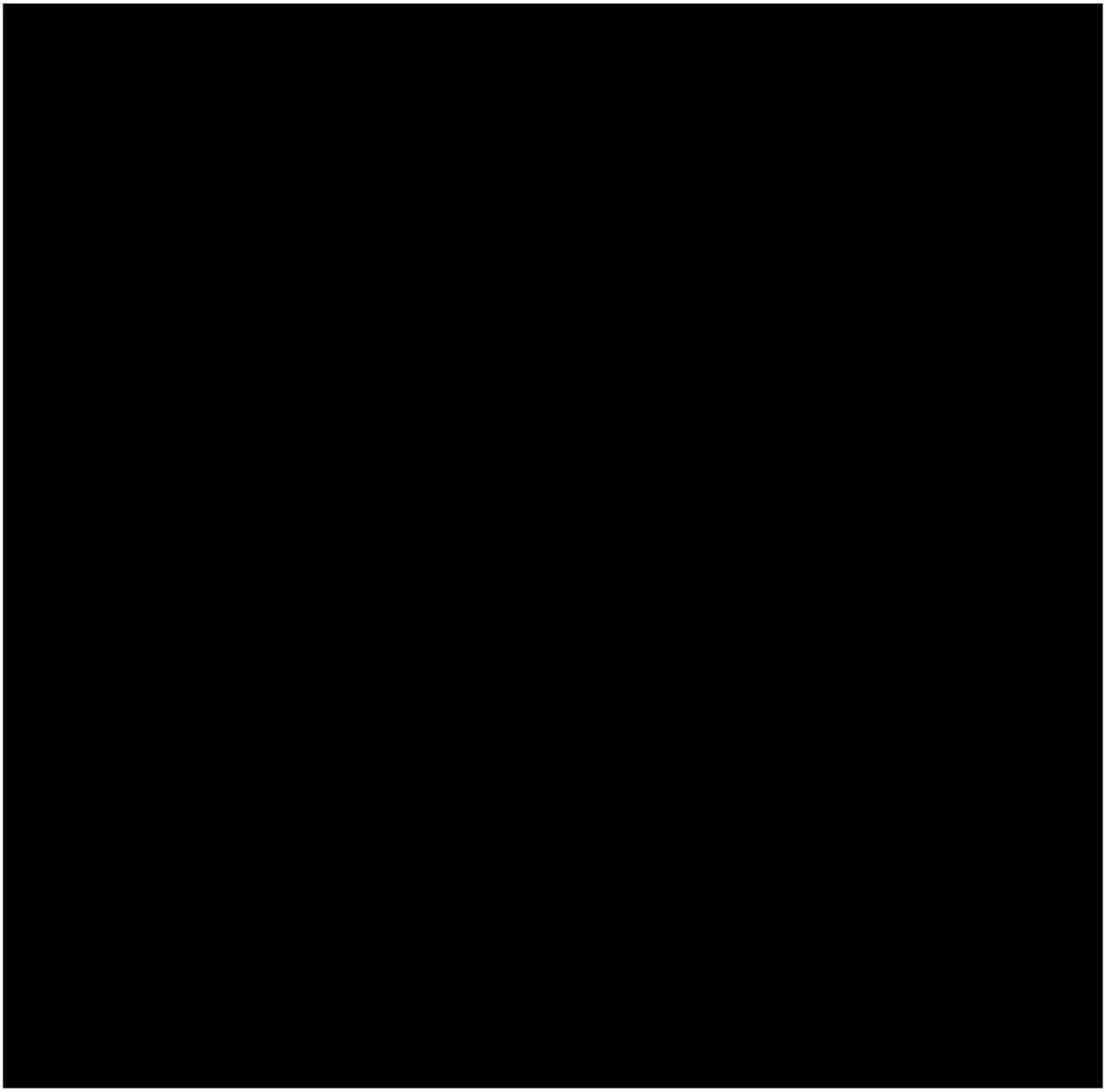
Administration of 4 doses (2 prior to mating and 2 during gestation) of BNT162b1, BNT162b2, or BNT162b3 elicited SARS-CoV-2 neutralizing antibody responses in the majority of females just prior to mating (M0), at the end of gestation (GD21), and at the end of lactation (LD21). SARS-CoV-2 neutralizing titers were detected in most offspring (fetuses on GD21 and pups on PND21). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals.

In conclusion, intramuscular administration of BNT162b1, BNT162b2 and BNT162b3 before and during gestation to female Wistar (CRL:WI[Han]) rats was associated with non-adverse effects (body weight, food consumption and effects localized to the injection site) after each dose administration. There were no effects of any of the 3 vaccine candidates on mating performance or fertility in F0 female rats or on embryo-fetal or postnatal survival, growth, or development of the F1 offspring. An immune response was confirmed in F0 female rats following administration of each vaccine candidate and these responses were also detectable in the F1 offspring (fetuses and pups).

3. INTRODUCTION

The objective of this study was to assess the potential effects of BNT162b1, BNT162b2 and BNT162b3, vaccine development candidates to prevent Covid-19, and the concomitant immune response, on fertility and pre and postnatal development in the female Wistar (CRL:WI[Han]) rat.

The design of this study was based on Guidelines from the International Conference on Harmonization, S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals; Department of Health and Human Services, Food and Drug Administration (FDA), 2006 Guidance on Developmental Toxicity Studies in Vaccines for Infectious Disease Indications; WHO guidelines on nonclinical evaluation of vaccines.



FOI 2289

Pages 14-37 have been removed under section 47 of the FOI Act.

10. CONCLUSION

Intramuscular administration of BNT162b1, BNT162b2 and BNT162b3 before and during gestation to female Wistar (CRL:WI[Han]) rats was associated with non-adverse effects (body weight, food consumption and effects localized to the injection site) after each dose administration. There were no effects of any of the 3 vaccine candidates on mating performance or fertility in F0 female rats or on embryo-fetal or postnatal survival, growth, or development of the F1 offspring.

An immune response was confirmed in F0 female rats following administration of each vaccine candidate and these responses were also detectable in the F1 offspring (fetuses and pups).

FOI 2289

Pages 39-1,145 have been removed under section 47 of the FOI Act.