Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3205705

Daniel
By Email: foi+request-7855-4b843fb6@righttoknow.org.au

Dear Daniel,

FREEDOM OF INFORMATION REQUEST FOI 3077
Request Consultation Process

1. I refer to your request dated 13 September 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you sought access to the following documents:

> *"I would like to request a copy of the information that this advice from the ACMS was based on. Specifically, I would like to request a copy of the ACMS' review into ivermectin including references to any scientific papers used in this review* ***(item 1).***
>
> *The update from Sept 10, also claims that the 3 - 4 fold increase in dispensing of ivermectin prescriptions in recent months is leading to national and local shortages for those who need the medicine for scabies and parasite infections* ***(item 2)****.*
>
> *My prescribing doctor informed me that the pharmacist compounding my prescription has recently taken delivery of a large amount of Ivermectin and has plenty in stock.*
>
> *I would therefore challenge the claim that there are local shortages of this drug and would like to request the evidence that this claim is based on* ***(also captured in item 2)****."*

Decision Maker

2. I am the Therapeutic Goods Administration (**TGA**) officer authorised to make a decision on your request under the FOI Act.

Request too voluminous to process

3. The TGA has now undertaken a preliminary search and retrieval for documents falling within the scope of your request. As a result, I can confirm that the scope of your request is too voluminous to process.

4. Regarding item 1 of your request, the TGA holds one relevant document. However, the TGA does not hold "*references to any scientific papers used in this review*" because scheduling through the Poisons Standard is based on public health and safety and does not include recommendations on the efficacy of medicines.

5. Regarding item 2 of your request, preliminary estimates suggest that the scope of your request includes 17 documents, containing approximately 2,841 pages. Each of these documents contains commercially valuable information. These documents will require consultation with third parties, including pharmaceutical sponsors and wholesalers. As a result, your request is too voluminous to process.

6. Given the scope of documents falling under your request, I am of the view that your request is too voluminous to process.

Requirement to undertake a request consultation process

7. Under paragraph 24(1)(a) of the FOI Act, I, as a decision maker must consult you if I am satisfied that a "practical refusal reason" exists in relation to your request. A practical refusal reason exists if the work involved in processing the request would substantially and unreasonably divert the resources of the TGA from its other operations. As mentioned above, I am of the view that a practical refusal reason exists in relation to your request.

8. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**. In deciding whether the processing of your request would involve a substantial and unreasonable diversion of resources such that a practical refusal reason exists, I am required under section 24AA(2) of the FOI Act to consider the resources that would have to be used in the following activities:
    - identifying, locating and collating the documents;
    - deciding whether to grant or refuse access to each document and/or to provide an edited copy which would include examining each document and consulting with any person (including those that I would be required to consult under the FOI Act);
    - making a copy or edited copy of each document; and
    - notifying any interim or final decision on the request (including to any third party consulted in the event that a decision is made to give access to the documents despite the objections of the relevant third party).

9. In coming to a view that a practical refusal reason exists in relation to your request, I have had regard to the following:
    - your request dated 13 September 2021.
    - the estimated volume of documents involved, and the work involved in processing them, for example, approximately 18 documents in total containing in excess of 2,847 pages.
    - each of the documents may contain commercially valuable information, that is likely to have a commercial value to the sponsor that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed. Consideration would need to be given to whether an exemption should be claimed and whether consultation with the relevant third party is required, and, if so, preparation of schedules for the third party detailing all relevant documents.
        - the number of affected third parties. There is likely to be at least seven third parties to consult, including numerous product sponsors and pharmaceutical wholesalers.
            - as you would appreciate, the TGA would need to write to each third party individually, attach copies of their documents, and consider the responses provided and any requested redactions.
            - I would then need to make a decision on these documents taking these submissions into account. Also, if any of the third parties objected to release of documents and I disagreed with them, then I would need to provide them with a decision.
    - the assumption that a substantial number of those documents may be capable of being made available (even if in edited form with exempt material redacted), the time taken to appropriately edit each document and to make copies.
    - the fact that any decision letter would need to list each document in an attachment setting out the outcome of the consideration of whether exemptions apply.

10. I consider that the number of pages estimated to fall within the scope of your request and the fact that much of the information is commercially valuable information, in addition to the

necessary consequential work associated with considering whether the documents may be lawfully disclosed, would have a substantial effect on the operations of the TGA.

11. I also find that the work involved in processing this request would be an unreasonable diversion of the TGA's resources. If these officers are required to consider large FOI requests, this diverts their time and attention from undertaking their primary role. In addition, the administrative team providing critical support to the TGA's evaluators and the other safety monitoring business of the TGA and the FOI team are also currently dealing with a high volume of COVID-19 related FOI requests. Processing your request would engage resources of those teams that would otherwise be supporting evaluators, the broader operations of the TGA's medicines safety monitoring business and processing other FOI requests. In this regard, the FOI Guidelines states that a relevant matter in deciding a practical refusal reason exists is "the impact that processing a request may have on other work in the agency or minister's office, **including FOI processing (emphasis mine)** (see paragraph 3.117 of the FOI Guidelines).

12. I also note that there are likely to be significant charges imposed on you for processing your request (as calculated in accordance with the *Schedule to the Freedom of Information (Charges) Regulations 2019*) based on the number of third parties.

Guidance on accessing the TGA's publicly available information

13. I note that paragraph 3.117 of the FOI Guidelines indicates another matter I may take into account in deciding whether a practical refusal reason exists is whether there is a significant public interest in the documents requested and what information is published. I consider that there is a public interest in evidence supporting the safety and efficacy of COVID-19 vaccines that will be used in Australia.

14. To a very large degree, the public interest is met through the TGA's publication of information relating to the decision to limit prescribing of ivermectin for COVID-19. The TGA has published a detailed statement which outlines the changes and the reasons for the decision in the *Notice of an amendment to the current Poisons Standard under paragraph 52D(2)(a) of the Therapeutic Goods Act 1989*, available at: https://www.tga.gov.au/scheduling-decision-final/notice-amendment-current-poisons-standard-under-paragraph-52d2a-therapeutic-goods-act-1989-0.

15. The TGA has also published a summary of its decision online at: https://www.tga.gov.au/media-release/new-restrictions-prescribing-ivermectin-covid-19.

16. Further information on the role, function, and members of the Advisory Committee for Medicines Scheduling (ACMS) is also publicly available at: https://www.tga.gov.au/committee/advisory-committee-medicines-scheduling-acms.

17. Therefore, I consider that insofar as any interest is served by the release of the documents in question, the public interest in evidence supporting the safety and efficacy of COVID-19 vaccines in Australia has already been met through the publication of the supporting regulatory documents and the publicly available materials outlined above.

18. I find that the balance of interests does not favour the expenditure of considerable resources by the TGA. The above diversion of TGA resources would, in my view, be substantial, and is likely to cause serious delays to, and potentially compromise, the TGA's performance of its regulatory functions under the *Therapeutic Goods Act 1989*.

19. Having regard to the importance of the prompt and proper performance of the TGA's regulatory functions, I consider that this diversion of resources would be unreasonable in the circumstances.

Notification of request consultation process

20. I am notifying you of my intention to refuse to give access to the documents that are within scope of your request.

21. Before deciding to refuse access to documents, I am required under paragraph 24(1)(a) of the FOI Act to undertake a request consultation process in accordance with section 24AB of the FOI Act and provide you with the opportunity to refine the scope of your request.

22. Accordingly, you are now afforded fourteen (14) calendar days from your receipt of this letter in which to contact the TGA to discuss a revision of the scope of your request.

23. Before the end of the 14-day consultation period, you must do one of the following:
    - withdraw your request;
    - make a revised request; or
    - indicate that you do not wish to revise your request.

24. One document within the scope of your request contains the substance of the commercially valuable information, would require consultation with numerous third parties and contains 2,780 pages. The majority of the information from this document which relates specifically to your request is summarised within subsequent documents included in your request.

25. As a result, you may wish to consider excluding the document containing 2,780 pages from the scope of your request (please note that this is a suggestion only and does not guarantee the practical refusal reason will no longer exist).

26. If you have not contacted the TGA within 14 days of receiving this letter to do one of the above or consulted the TGA to discuss revising its scope, your request is taken to have been withdrawn.

27. If you wish to refine the scope of your request, you may contact the TGA FOI team on (02) 6289 4630 or at TGA.FOI@tga.gov.au.

28. Please note that if you indicate that you do not wish to revise your request or revise your request in such a way that I am still of the view that processing it would substantially and unreasonably divert TGA resources from other operations, I may refuse your request under paragraph 24(1)(b) of the FOI Act.

Yours sincerely,

Authorised and electronically signed by

Benjamin Noyen
Assistant Secretary
Regulatory Engagement Education and Planning Branch
Therapeutic Goods Administration
Department of Health
12 October 2021