Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Will B
Email: foi+request-11599-b5c482c2@righttoknow.org.au

Dear Will

FREEDOM OF INFORMATION REQUEST FOI 5242
Request Consultation Process

1. I refer to your request dated 2 July 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

   "*I am seeking access to all correspondence, including briefs, emails, meeting records and other documents between the Therapeutic Goods Administration and Saluda Medical Pty Ltd as part of the TGA's Post-market review of spinal cord stimulation (SCS) devices between 1 December 2023 and 23 June 2024.*

Decision Maker

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

Requirement to undertake a request consultation process

3. Before deciding on the outcome of your request, I have decided 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.
4. For the reasons outlined in this letter, I am satisfied that, because of the number of documents involved in your request, the number of third parties that would need to be consulted, and the number of hours involved in considering exemptions and making a decision on the documents as set out above, your request would substantially and unreasonably divert staff in regulatory areas of the TGA who would be required to review and consider the documents and any submissions provided by third parties on the documents, from the performance of their day-to-day functions.
5. The TGA has now undertaken a preliminary search and retrieval for documents coming within the scope of your request. As a result, TGA officers have indicated that there are in excess of 92 relevant documents with more than 1,166 pages that would have to be processed for your request to be finalised.
6. 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.
7. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**.

8. 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 subsection 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 document).

9. In coming to a view that a practical refusal reason exists in relation to your request, I have had regard to the following:

   - the correspondence from you dated 2 July 2024, including the terms of the FOI request;
   - the estimated volume of documents within scope of your request and the work involved in processing them. Namely, preliminary estimates from the relevant line areas of the TGA identified approximately 92 documents containing more than 1,166 pages in relation to your request;
   - the need to prepare a schedule detailing all relevant documents;
   - that each of the documents may contain business and/or personal information, in relation to which, consideration would need to be given about whether an exemption should be claimed and whether consultation with third parties is required, and, if so, preparation of schedules for the third party detailing all relevant documents;
   - the requirement to consult with the relevant third party. As you would appreciate, the TGA would need to write to the third party, 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 the third party objected to release of documents and I disagreed with them, then I would need to provide them with a decision;
   - that advice on the data and sensitivity of the information in these documents would need to be provided by specialised technical staff at the TGA (i.e., senior clinical medical officers), a majority of whom are presently engaged in consideration of at least one other application for registration of medical device as well as reasonably regular applications for variation of existing registrations of medical devices;
   - 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;
   - that any decision letter would need to list each document in an attachment setting out the outcome of the consideration of whether exemptions apply; and
   - the need to prepare a third-party decision letter and associated schedules, should the third party object to the proposed release of their information.

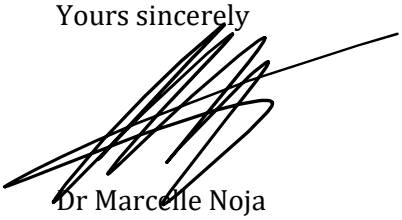
10. Considering these matters, I have prepared an estimate of the time required to process your request. For that purpose, I have:
    - considered the time taken to consult with the relevant third party;
    - considered the time already taken to perform searches for potentially relevant documents and the additional time required to complete the remaining searches; and
    - estimated how long it might take to process 92 documents containing approximately 1,166 pages.
11. The estimate of charges calculator has calculated that the processing of this request could take at least 71 hours. I consider that the number of documents and the number of pages estimated to fall within the scope of your request, combined with the fact that much of the information is commercially confidential information and 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.
12. I also find, for the following reasons, that the work involved in processing this request would be an unreasonable diversion of the TGA's resources, including TGA's officers engaged in evaluation and assessment of medical devices. As you would appreciate, if these officers are required to consider large FOI requests, this diverts their time and attention from undertaking their primary role.
13. In addition, the administrative team providing critical support to the TGA's evaluators and the other regulatory operations of the TGA. Processing your request would engage resources of those teams that would otherwise be supporting evaluators, and the broader operations of the TGA. 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 (see paragraph 3.117 of the FOI Guidelines).
14. The time to review the 92 documents in detail to determine whether any of the documents or parts of the documents could be characterised as exempt, and then redacting the material, would be a substantial and unreasonable diversion of the TGA's resources.
15. I find that the balance of interests does not favour the expenditure of considerable resources by the TGA. I am satisfied that the diversion of resources to provide documents in response to your request is not reasonable.

Notification of request consultation process

16. As outlined above, I have decided 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.
17. 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. The processing time for your request has been set aside to allow for the request consultation period.
18. 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.

19. You may wish to consider the following suggestions and exclusions of the scope of your FOI request (please note that these are suggestions only and do not guarantee the practical refusal reasons will no longer exist):
    - Remove the wording 'other documents' from the scope
    - Requesting a specific document or documents.
20. Should you require further time to consider submitting a revised scope, you are welcome to request an extension to the consultation period in writing to the TGA, in accordance with subsection 24AB(5) of the FOI Act.
21. 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 your scope, your request is taken to have been withdrawn.
22. If you wish to refine the scope of your request, you may contact the FOI team on (02) 6289 4630 or at TGAFOI@health.gov.au.
23. 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



Dr Marcelle Noja
Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
08 July 2024