Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: D19-6020153

Ms Shanna Miller

Email: foi+request-5575-07576313@righttoknow.org.au

Dear Ms Miller

FREEDOM OF INFORMATION REQUEST FOI 1277
Request Consultation Process

I refer to your request dated 13 August 2019 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 hereby request the release of documents held by the Therapeutic Goods Association for the purposes of Freedom of Information Act 1982.*
>
> *Documents requested:*
>
> *All reports providing evidence of safety and efficacy that were used to approve the licensure of the Infanrix hexa, Infanrix IPV, Quadracel, Boostrix, Infanrix, and Tripacel vaccines.*
>
> *Please also include the above requested reports for any previous versions of vaccines for Pertussis, Diphtheria and Tetanus, not currently on the NIP."*

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

The TGA has now undertaken a preliminary search and retrieval for Infanrix documents coming within the scope of your request. As a result, TGA officers have indicated that there are approximately 48,000 relevant pages that would have to be examined for the six vaccines nominated in your request (not including previous versions of vaccines which are not currently on the NIP).

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.

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 entitled 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 document).

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 of 13 August 2019, including the terms of the FOI request;
- the estimated volume of documents involved and the work involved in processing them. Preliminary estimates from the relevant line areas of the TGA identified 10 offsite archive boxes, each containing at least 1,200 pages each for Infanrix alone (i.e. an approximate total of 12,000 pages). A search and retrieval has not been undertaken for the five other vaccines mentioned in your request, nor the previous versions of vaccines not currently on the NIP (but each vaccine is likely to yield similar results);
- the amount of time that would be required to examine all files to identify, in the first instance, the portions of the application dossier which contain the most relevant documents, for each vaccine;
- there are additional areas where searches have not been completed which are likely to have additional relevant documents and therefore the total number of relevant documents is likely to be higher than the estimate;
- the need to prepare a schedule detailing all relevant documents;
- the fact that each of those 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 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; and
- the need to prepare at least two (2) third party decision letters and associated schedules per current vaccine (i.e. 12 third parties), should any third parties object to the proposed release of their information.

Taking into account these matters, I have prepared an estimate of charges in relation to your request. For that purpose, I have:

- taken a conservative approach of attributing 2,400 pages of potentially relevant data associated with the current vaccines in this request (this does not include the previous versions of vaccines);
- considered the time required to undertake the consultation process with the two (2) potential third parties per current vaccine, that is, a total of 12 third parties;
- considered the time already taken to perform searches for potentially relevant documents and the additional time required to complete the remaining searches.

Based on my conclusion that the processing of your request could take in excess of 330 hours, I consider your request to be an unreasonable diversion of the TGA's resources to process in its current form. Further, I estimate that the charges that may be 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 estimated number of hours, may exceed $6,108.33.

Notification of request consultation process

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

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.

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.

Accordingly, you are now afforded fourteen calendar (14) days from your receipt of this letter in which to contact the TGA to discuss a revision of the scope of your request. If you wish to refine the scope of your request you may contact the FOI team on (02) 6289 4630 or at TGA.FOI@tga.gov.au.

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.

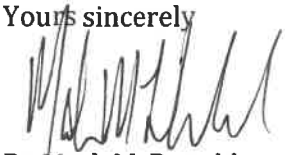
You may wish to consider the following suggestions to revise the scope of your FOI request (please note that these are suggestions only and do not guarantee the practical refusal reasons will no longer exist):

- requesting copies of TGA clinical evaluation reports prepared for one or more of the vaccines of interest; and/or
- requesting copies of clinical summary documents prepared by the TGA for the relevant advisory committee at the time of application for one or more of the vaccines of interest; and/or
- limiting the request to the nominated reports for one (or more) of the current NIP vaccines and removing the reference to previous versions of diphtheria, pertussis and tetanus vaccines which are no longer on the NIP.

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.

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 Mark McDonald
Senior Manager
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
10 September 2019