



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

Mr Kristof Wing  
Email: [foi+request-787-e398254d@righttoknow.org.au](mailto:foi+request-787-e398254d@righttoknow.org.au)

Dear Mr Wing

**FREEDOM OF INFORMATION REQUEST FOI 091-1415**  
**Request Consultation Process**

I refer to your request dated 28 October 2014 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

*"I am requesting any of the following from between 01 January 2014 and today, 28 October 2014, regarding Ranbaxy Laboratories Ltd and its international subsidiaries:*

- Any Internal Communications, including emails and letters, regarding the regulatory actions of and results of inspections undertaken by the Food and Drugs Administration or Health Canada of facilities owned and/ or managed by Ranbaxy and its subsidiaries,*
- Internal Communications, including emails and letters, regarding the safety of pharmaceuticals produced by Ranbaxy and its subsidiaries which have previously received regulatory approval."*

**Decision Maker**

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 documents coming within the scope of your request. As a result, TGA officers have indicated that there are 164 documents containing approximately 650 relevant pages that would have to be processed for your request to be finalised.

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:

- 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 28 October 2014, 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 164 documents containing approximately 650 relevant pages;
- the need to prepare a schedule for 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;
- on 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 any third party decision letters and associated schedules, should any third parties object to the proposed release of their information.

On the basis of the preliminary search and retrieval indicated above, a preliminary estimate of charges was undertaken (using the charges calculator tool originally prepared by the Australian Government Solicitor) which indicated that it would take 176.6 hours to process your request.

In accordance with paragraph 3.106 of the FOI Guidelines, I asked a TGA departmental officer to undertake a more accurate estimate by sampling a reasonable selection of the documents indicated as being within the scope of your request.

For that purpose, I have:

- considered the actual time spent to date on searching for and retrieving documents for the purposes of your request, being **15.3 hours**; and
- estimated, based on past experience with similar consultations, the amount of time needed to consult seven (7) third parties, including reviewing and redacting documents on which the TGA is considering for release and exemptions, being **21 hours** (based on an average of 3 hours to prepare consultation letters and schedules per consultation);
- estimated the amount of decision making time that would be required in processing your request, based on a random sample of 6 documents (totalling 26 pages), including all the tasks outlined in the previous paragraph. As the sample indicated that approximately 6 minutes decision making time would be required per page, I then extrapolated my estimate of the total time it would take to process these documents to the approximate total number of pages referred to above that are estimated to be within the scope of the request, being **65 hours**; and



- estimated the amount of time that would be required to prepare schedule(s) of documents and finalise decision(s), being **5 hours** (for the purposes of this letter I have assumed that no third party schedules or decisions would be required, but it is possible that the TGA would require additional time if these were required).

Therefore, I estimate that the total processing time for this request would be approximately **106 hours**. On the basis of a departmental officer working 38 hours per week, 106 hours would equate to approximately 3 weeks full time work to process the request.

#### **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 (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 Elizabeth Santolin on (02) 6232 8664.

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.

If you have not contacted the TGA within 14 days of receiving this letter to do one of these things 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 Larry Kelly  
Head, Monitoring and Compliance Group  
Therapeutic Goods Administration

25 November 2014