Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D22-5034675

Jaay-H
Email: foi+request-8079-b3375f36@righttoknow.org.au

Dear Jaay-H

FREEDOM OF INFORMATION REQUEST FOI 3407
Notice of Decision – Request for a waiver of charges

1. I refer to your request dated 8 November 2021 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

> *"Please provide a document recording the number of serious adverse events reported following covid-19 vaccine injection in Australia to date (7/11/2021). As vaccine pharmacovigilance goes, an adverse event following immunisation is considered serious if it results in:*
> *+ death*
> *+ is life-threatening*
> *+ requires inpatient hospitalisation*
> *+ prolongation of existing hospitalisation persistent or significant*
> *+ disability/incapacity congenital anommoly/birth defect"*

Background

2. On 8 November 2021, the TGA received a request from you under the FOI Act.
3. On 6 December 2021, the TGA advised you of the overall number of adverse event reports related to COVID-19 vaccines. As you were provided the information requested in the scope of your FOI request, the TGA invited you to confirm whether this information satisfied your request, and, accordingly, whether you agreed to withdraw your request. I note that you did not respond to this correspondence.
4. As no response was received from you, the FOI team continued processing your request. Accordingly, on 8 December 2021, you were advised that the costs associated with processing your request amounted to $65.22, and you were asked to:
    - pay the charge, being the deposit outlined above, and notify the FOI Team; or
    - notify the TGA that you wish to contend that:
        - the charge had 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.

5. On 17 December 2021, the TGA received a request from you for a waiver of charges on public interest grounds, as follows:

> *"The Australian public have a right to know the number of serious adverse events reported following covid-19 vaccine injection.*
>
> *Under section 8 of the Charges Regulations an agency has discretion to not impose a charge. I contend that the charge should not be imposed in accordance with Section 29(1)(c) of the FOI Act. Please take into account that giving access to the documents in question is in the general public interest and in the interest of a substantial section of the public.*
>
> *The agency (TGA) and the Department of Health have not been providing this information to the Australian public. The agency has also disabled the export function on their Database of Adverse Event Notifications making it impossible for the Australian public to export the data for assessment and analysis. Until the agency begins to regularly disclose the number of serious adverse events following covid-19 vaccine injections the Australian public will have to continue to rely requests made under the FOI Act for such information."*
>
> *It is unreasonable and at odds with the FOI Act's objects to expect the Australian public to pay money to receive this very critical information.*

Decision Maker

6. I am the TGA officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

7. I have decided not to waive the charges that can be imposed for the processing of your FOI request.

Material Considered in Decision-Making

8. In coming to my decision, I had regard to the following:
    - your request for documents under the FOI Act dated 8 November 2021;
    - my initial decision of 8 December 2021 to impose charges of $65.22;
    - the correspondence from you dated 17 December 2021, requesting that the charges be waived as access to the documents is in the public interest;
    - the FOI Act and, in particular, section 29 of the FOI Act; and
    - the guidelines issued by the Australian Information Commissioner under section 93A of the FOI Act (FOI Guidelines).

Reasons for Decision

9. In considering a request that charges not be imposed, subsection 29(5) of the FOI Act provides:

> *Without limiting the matters the agency or Minister may take into account in determining whether or not to reduce or not to impose the charge, the agency or Minister must take into account:*
> *(a) whether the payment of the charge, or part of it, would cause financial hardship to the applicant, or to a person on whose behalf the application was made; and*
> *(b) whether the giving of access to the document in question is in the general public interest or in the interest of a substantial section of the public.*

10. In addition, Part 4 of the FOI Guidelines sets out the matters I must have regard to in considering a request not to impose a charge.

11. In making this request for a waiver of charges, you have not made submissions relating to your current financial affairs or provided any evidence of financial hardship, and, furthermore, you have not requested a waiver or reduction of charges on financial hardship grounds.

12. Therefore, currently, there is insufficient evidence for me to be satisfied that payment of the charge would cause you financial hardship.

Public Interest

13. In considering whether granting access to the documents would be in the public interest or in the interest of a substantial section of the public, the FOI Guidelines note that it is important to identify the 'general public interest' or the 'substantial section of the public' that would benefit from disclosure.

14. In considering the public interest, paragraph 4.109 of the FOI Guidelines sets out a non-exhaustive list of examples in which it may be appropriate to reduce or waive a charge. The factors that may be relevant to your request include the following:

    - the documents relate to a matter of public debate, or to a policy issue under discussion within an agency, and disclosure will assist public comment on, or participation in, the debate or discussion; and
    - the documents relate to an agency decision that has been a topic of public interest or discussion, and disclosure of the documents would better inform the public as to why or how the decision was made, including highlighting any problems or flaws that occurred in the decision-making process.

15. In your submission you indicated that there is public interest in the disclosure of the documents for the following reason:

    "The Australian public have a right to know the number of serious adverse events reported following covid-19 vaccine injection."

16. I note that the TGA FOI Team advised you on 6 December 2021 of the overall number of adverse event reports related to COVID-19 vaccines which were either categorised as a serious adverse event or which reported that the person experiencing the adverse event was hospitalised.

17. I do agree that, in light of the current pandemic, there is public interest in adverse event information related to vaccinations for COVID-19. However, in my view, the public interest has been met, to a very large degree, by the information that is already publicly available on the TGA website, including the Database of Adverse Event Reports **(DAEN)**. The DAEN contains information from all reports of adverse events that the TGA has received in relation to medicines, including vaccines, used in Australia

18. Reporting of an adverse event and publication of an adverse event in the DAEN does not mean the event was related to the vaccine. Expert analysis and review of adverse event reports is needed to determine whether there may be a link between reported events and vaccination.

19. All adverse event reports are used by the TGA equally in our monitoring of product safety. As such, it is my view that the total number of adverse event reports classified as 'serious' does not provide significant information in terms of assessing vaccine safety beyond that which is already publicly available. The TGA analyses adverse event report data and reviews individual reports to identify possible safety issues for investigation. If these investigations confirm a safety signal, the TGA takes appropriate

action. This includes taking prompt action to make this information available to health professionals and the public.

20. Further information about the safety of medicines and how the TGA monitors safety is available here: https://www.tga.gov.au/medicines-safety.

21. Furthermore, the TGA publishes a COVID-19 weekly safety report which contains information about adverse events following immunisation. This can be accessed at https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

22. In your submission, you also noted that:

> *"The agency has also disabled the export function on their Database of Adverse Event Notifications making it impossible for the Australian public to export the data for assessment and analysis."*

23. I wish to inform you that the information currently contained on the DAEN can be extracted by copying and pasting the List of Reports table into your desired form. You can do this by setting the number of 'Records to display' to the highest value, '500', and then copying the List of Reports table and pasting into an Excel spreadsheet.

24. On that basis, I am satisfied that insofar as there is a general public interest in "*available and transparent*" information about adverse event reports received for COVID-19 vaccines, this interest is satisfied by resources in the public domain which are regularly updated by the TGA including the DAEN and the weekly safety report.

25. Therefore, given the publicly available information already published in relation to the COVID-19 vaccinations, I am not satisfied that a substantial section of the public may benefit from the disclosure of this information.

Conclusion

26. For the reasons outlined above, I have decided not to waive the charges that apply to the processing of your request.

27. In my view, this approach balances the potential public interest in this matter with the intent of the FOI Act that charges can be imposed for processing FOI requests.

28. Please note my decision not to waive the charges will apply to the **final amount** of charges that can be imposed. Under the *Freedom of Information (Charges) Regulations 2019* (the Charges Regulations), once an FOI request is complete, the TGA is required to determine the **actual** charges that can be imposed under the Charges Regulations associated with processing the request. This final amount may be higher or lower than the estimated charges.

29. In the event the final charge is less than the estimate, you will be refunded the difference. If the final charges exceed the estimate (and my decision is to give you full access to all relevant information) regulation 10(2) allows me to charge the actual cost. If any information is exempt, a higher amount cannot be imposed.

Time limit for processing your FOI request

30. 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 of $20.00.

31. Under subsection 29(1) of the FOI Act, you have 30 calendar days from receipt of this notice to:

    - pay the charge, being the deposit or full amount outlined above, and notify the FOI Team via the email below; or
    - seek an internal review of this decision; or

- notify the TGA that you withdraw your request.

32. 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.

Review and Complaint Rights

33. 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/

34. If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Signed electronically

Dr Claire Larter
Director
Pharmacovigilance Branch
Therapeutic Goods Administration
13 January 2022