HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

28 August 2023

[redacted]
[redacted]com
Sent by email

Re: Freedom of Information request FOI 23/07/004

I refer to the request which you made under the Freedom of Information (FOI) Act 2014 for records held by the Health Products Regulatory Authority (HPRA), on 28 July 2023 and the HRPA acknowledgement letter sent to you on the 8 August 2023.

Your request sought the following information:
"

1. *Under the Freedom of Information Act I would like to request COVID-19 batches numbers which are associated with suspected reactions below, and number of each recorded adverse events (how many people experienced each suspected adverse reaction?):*
2. *1 death*
3. *2 COVID-19*
4. *3 myocarditis*
5. *4 blood cloths (trombosis venosa and other)*
6. *5 cardiac arrest*
7. *6 stroke*
8. *7 miscarriage"*

The HPRA has now reviewed your request and discussed the records you seek. We must now advise that we must refuse your request as presently formulated. We refer you to 15 (1)(c) of the FOI Act.

Under s.15(1)(c) Freedom of Information Act, 2014, an FOI request may be refused on the following basis:

> *15. (1) A head to whom an FOI request is made may refuse to grant the request where—*
> ...
> *(c) in the opinion of the head, granting the request would, by reason of the number or nature of the records concerned or the nature of the information concerned, require the retrieval and examination of such number of records or an examination of such kind of the records concerned as to cause a substantial and unreasonable interference with or disruption of work (including disruption of work in a particular functional area) of the FOI body concerned*

The request as presently formulated, specifically in relation to the batch numbers, would, by reason of the high number and nature of the records concerned, cause a substantial disruption to the work of the Human Products Monitoring (HPM) Department.

While the HPRA routinely receives COVID-19 vaccine batch numbers as part of suspected adverse reaction reports, which are recorded in the national database, to retrieve this information each individual report needs to be opened and the information extracted.
This is an extremely time-consuming activity and therefor considered voluminous. It is therefore not possible to process such requests and not at the volume covered in your request at this time.

The HPRA requests that, as an alternative to refusing the request, it is refined. Under s.15(4) of the FOI Act, where we seek to rely on s.15(c) as grounds for refusal, we are obliged to assist or offer to assist you to refine or amend your request such that it no longer falls to be refused under s.15(c).

Therefore, in relation to making this request more specific, we would propose to refine your request as outlined below:

In relation to your request for number of each recorded adverse events (how many people experienced each suspected adverse reaction?):

1. *death*
2. *COVID-19*
3. *myocarditis*
4. *blood cloths (trombosis venosa and other)*
5. *cardiac arrest*
6. *stroke*
7. *miscarriage*

However, please note that this information is in the available publicly and therefore refused under the Freedom of Information Act 2014 on the grounds of Section 15(1)(d):

A head to whom an FOI request is made may refuse to grant the request where —
(d) the information is in the public domain.

Please see the information listed below to allow you to access the information that is in the public domain.

As you are aware, the HPRA, as the regulatory authority in Ireland for medicines and other healthcare products, operates the national adverse reaction (side effect) reporting system for submission of reports associated with medicinal products, including vaccines. Through this reporting system, the HPRA receives reports on a voluntary basis from healthcare professionals and members of the public. By way of background, adverse reaction reports received by the HPRA are processed and entered into the national database, with reports subsequently sent to EudraVigilance the European Medicines Agency's (EMA's) database of suspected adverse reactions, where the data are analysed to detect new safety signals. Anonymised data from these adverse reaction reports are publicly accessible for review at www.adrreports.eu. Should you wish to search this database for additional information, the following tips on searching may be helpful:

- Please click on this link www.adrreports.eu
- Click 'en'
- To consult the reports for COVID-19 vaccines, follow this **link**, then click on the letter 'C' and scroll down until "COVID-19".
- Different information is available under different tabs such as 'Number of individual cases received over time' and 'Number of individual cases by EEA countries' etc.

Separately, you might be interested to note that the European Medicines Agency (EMA) have also commenced publishing Periodic Safety Update Reports (PSUR) for authorised COVID-19 vaccines. The PSUR is a pharmacovigilance document intended to provide an evaluation of the risk-benefit balance of the medicinal product during the reference period mentioned. In addition, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) assessment of those PSUR reports is also being published. The relevant information for Comirnaty can be found here Comirnaty | European Medicines

Agency (europa.eu). We expect the publication of the corresponding reports for Spikevax in the next month and publication for other COVID-19 vaccines in due course.

3. Rights of appeal

In the event that you object to this decision you may appeal it. You can make such an appeal by writing to the Chief Executive, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Terrace, Earlsfort Centre, Dublin 2 or by sending an e-mail to foi@hpra.ie .

You should make your appeal within 20 days (4 weeks) from the date of this notification, where a day is defined as a working day excluding the weekend and public holidays. However, the making of a late appeal may be permitted in appropriate circumstances. The appeal will involve a complete reconsideration of the matter by the Chief Executive of the HPRA.

Yours sincerely,

HPRA Freedom of Information Officer