Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

30 April 2024

Dear [redacted]

FOI 24/331

Thank you for your information request dated 5 April 2024 where you asked:

> "*I have wrote to Pfizer with relation to the below question:*
>
> *I am writing in relation to the data in the 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021*
>
> *It states that in 3. RESULTS*
> *3.1. Safety Database*
> *3.1.1. General Overview*
> *It is estimated that approximately 126,212,580 doses of BNT162b2 were shipped worldwide*
> *from the receipt of the first temporary authorisation for emergency supply on 01 December*
> *2020 through 28 February 2021.*
>
> *However does your data set use the 128,212,580 as administered doses for the percentage Adverse reactions or do you use the actual administered doses . If it is the latter do you have the actual administered doses for this data set you have published .*
> *As administered doses are not the same as shipped doses*
>
> *The our world in our data shows that only around 54 million doses were actually administered by the time the data set was completed and published by yourselves @ 28th Feb*
> *USA 38.43M*
> *Italy 3.96M*
> *Germany 5.65M*
> *France 4.3M*
> *Portugal 797K*
> *Spain 3.4M*

Can you please clarify the actual administered vaccine figure worldwide used in this post authorisation data

However there response was that it was out of the medical scope and to contact my Dr

However the only data the Dr will have is the green book which does not contain the information I am seeking

Therefore under the foi can you please send me the information I seek ."

For clarity, we identify your two questions made under the Freedom of Information Act as being:

"However does your data set use the 128,212,580 as administered doses for the percentage Adverse reactions or do you use the actual administered doses . If it is the latter do you have the actual administered doses for this data set you have published .
As administered doses are not the same as shipped doses"

And:

"Can you please clarify the actual administered vaccine figure worldwide used in this post authorisation data"

Please note that while the MHRA regularly review safety information from the COVID-19 vaccine manufacturers, the specific Pfizer document you refer to has not been submitted to the MHRA as part of the regulatory process.

In relation to your requests about administered vaccine doses for the dataset and the administered vaccine figure worldwide used in the document you refer to you, we can confirm that the MHRA does not hold this information.

We recently wrote to you in response to a different request, FOI 24/246. In that request also, some questions you asked were about information which was not held by the MHRA; we have therefore again included the links to the Information Commissioner's website, where you can find guidance about what is and is not in scope of the FOIA, and advice on how to word an effective information request.

We are including the link to the ICO's guidance on when information is covered by the FOIA:

https://ico.org.uk/for-organisations/foi/what-is-the-foi-act-and-are-we-covered/#:~:text=The%20Act%20covers%20all%20recorded%20information%20held%20by,notes%2C%20recordings%20of%20telephone%20conversations%20and%20CCTV%20recordings

This guidance explains that there is no requirement on FOI to comment or provide views in response to a request, if those views are not already held in recorded form:

The Act does not cover information that is in someone's head. If a member of the public asks for information, you only have to provide information you already have in recorded form. You do not have to create new information or find the answer to a question from staff who may happen to know it.

We also draw your attention to the ICO's 'top tips' for making a request, and advice on 'Protecting public money' which are available here:

https://ico.org.uk/for-the-public/official-information/

Top tips

To make information requests as efficiently and effectively as possible, we suggest you take this approach:

i. ***Search first.*** *Public authorities publish a great deal of information. You may find what you're looking for by searching online or looking at the website's sitemap. If the information is already in the public domain, it may be quicker to find it than ask for it.*
ii. ***Keep it clear.*** *Make your request as simple and straightforward as possible. Use simple language. Numbered lists or bullet-points might help you to structure your request. In general, try to make it as easy as possible for the public authority to understand what you want to receive.*
iii. ***Be nice.*** *Even if you're dissatisfied with the organisation, try to put that to one side and focus on the information you want to receive. If possible, keep your information request separate from any ongoing email threads or complaints about wider issues.*
iv. ***Read it twice.*** *Before you send a request, take another look at it to make sure it's clear and easy to follow. If you're unsure, you could seek a second opinion from someone you know. They might spot something confusing that you can fix before you send the request. If the public authority has to ask you to clarify your request, it will take longer for you to receive the information you want.*

Protect public money

Gaining access to public information is your right and public bodies must respect that.

However, requests do cost public bodies time and money to respond to. This is public money and we need to make sure it's spent responsibly.

It is important that you don't submit frivolous or trivial requests.

You should not make requests for the same information more than once, unless the information has changed a lot.

You should not make requests as a way of 'punishing' a public body if you think they have done something wrong. If you do any of the above, the public body could consider your request vexatious and refuse to action it.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the agency who has not previously been involved in your request. If you wish to pursue that option, please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF