Medicines & Healthcare products Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

31 October 2023

Dear [redacted]

FOI 23/731

Thank you for your request for information dated, 3 October 2023, where you asked:

> "This FOI requests copies of all communications between the MHRA and Pfizer between the period 1 October 2020 and 30 March 2021, that record discussions on the Pfizer/BioNTech Covid-19 vaccine (BNT162b2) manufactured by Process 2.
>
> This information is to understand how the Pfizer/BioNTech Covid-19 vaccines manufactured by Process 2 were used, for example:
>
> - Did the MHRA shared the concerns of the EMA who wanted to include Process 2 vaccines in the Pfizer clinical trials?
> - The decisions around where Process 2 vaccines were supplied.
> - Were Process 2 vaccines used in the UK and globally?"

MHRA may hold information relevant to your request.

Section 12(2) of the FOIA means public authorities are not obliged to comply with a request for information if it estimates the cost of complying would exceed the appropriate limit. The appropriate limit for MHRA is set at £600, which represents the cost of one person spending 24 working hours determining whether we hold the information.

In this instance, we identified a consolidated assessment report which includes information related to manufacturing processes; Process 1 and Process 2. We also identified two email accounts of a previous members of staff which we expect will hold information on Process 1 and 2. The email account file size of one of these accounts was over 40 gigabytes and we expect the other account with be of a similar size. The process of email recovery and download when combined with the estimated time to locate only the emails relevant to this request, crossed the limit of Section 12.

Advice and assistance
Although we cannot answer your request at the moment, we may be able to answer a refined request within the cost limit.

The FOI guidance instructs that when applying Section 12 the entire request should be refused. You may wish to consider, for example, narrowing the request to the three questions raised as bullet points.

We suggest that any refined request is made for the purposes of any (rather than all) information MHRA hold which addresses these questions. This negates the need to search the legacy email accounts and therefore, the time taken for us to provide information which answers to these questions is very unlikely to result in another Section 12 refusal.

Please be aware that we cannot guarantee at this stage that a refined request would fall within the FOIA cost limit, or that other exemptions will not apply.

Yours sincerely,

Healthcare, Quality, and Access (HQA) FOI Team
Medicines and Healthcare products Regulatory Agency