Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA

10 South Colonnade
Canary Wharf
London E14 4PU
United Kingdom

www.gov.uk/mhra

18th January 2021

Dear Mr Newton

FOI request (FOI 20/442)

I am writing in response to your request for a review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') reply to your FOI request (FOI 20/442).

The purpose of this review is to determine whether the Agency dealt properly and fairly with your request under the Freedom of Information Act (FOIA). In particular, it will examine the reasons why information was withheld from you.

Your original request and the Agency's response are annexed.
I have carefully considered the correspondence and the points you make in your request for a review.

The Agency considered the information requested in the first part of your FOI request and we provided the redacted contract, subscription agreement and statement of works. Following this review, it can be confirmed that the MHRA has complied with all government requirements with regards to publicly available information for such contracts and that the draft response was internally scrutinised by the MHRA business and commercial teams. I have reviewed the redacted areas of these documents noting that the general outline of the contract has been provided but in all documents, commercially sensitive and personal data information has been removed such as names, timelines, details on processes and any other information that could be used by competitors. I considered that the commercially sensitive information was exempt from disclosure under 43 of the FOI Act and, following considerations of the public interest arguments in releasing this information, I support the conclusion that we cannot see any public interest argument that outweighs potential commercial harm. I therefore find that the reductions of texts in these documents were properly applied and the required procedures were followed.

The Agency considered your request for information determining the anticipation of COVID-19 vaccine Adverse Drug Reactions (ADRs) and details of the anticipated ADRs. You were informed that with any major new vaccination campaign, the MHRA always develops a proactive vigilance strategy and you were informed that we will take every report of a suspected side effect seriously based on our experience with other medicines and vaccines. With respect to the anticipated volume of suspected ADR reports for any forthcoming COVID-19 vaccination programme, the Agency replied that this has been estimated from a number of previous vaccination campaigns and you were informed that based on past new immunisation campaigns, we tend to receive around 1 Yellow Card report per 1,000

doses administered and we were preparing our surveillance systems on that basis. In review of this response, the content in this section endeavoured to provide an overview of the MHRA's proactive vigilance strategy including ADR assessment process using Yellow card reports and provided you with a rationale for the anticipated ADRs to the Covid vaccine at the current time

You asked to be provided a list of active and inactive ingredients so far known to be contained in the Pfizer vaccine. At the time you were given a link to the information available in the public domain. It was considered that for a vaccine that was at the stage of clinical trials, the list of ingredients requested, other that in the public domain, was exempt under Section 41 (information provided in confidence) and Section 43 (commercial interests) of the Freedom of Information (FOI) Act. Nevertheless, the vaccine has now been licensed and the Public Assessment Report contains an extensive section on quality aspects of the products (pages 7-13) in the following link.

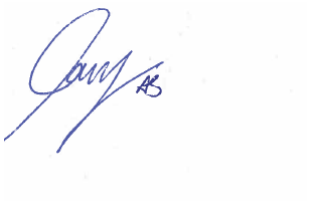
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/944544/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR___PFIZER_BIONTECH__15Dec2020.pdf

In conclusion, I have carefully considered the correspondence and the points you make in your request for a review but I do not consider that an adequate justification has been made to change the Agency's position. The use of the exemption and the reasoning why this applied were clearly set out in the original response to your FOI request.

If you remain dissatisfied, you may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. The ICO's address is:

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

Yours sincerely



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