FOI 21/632 CSC 53240 Freedom of Information Request

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MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Wed 16/06/2021 12:05 AM

To: You

Dear Dr [redacted]

Thank you for your email.

1. Any documents requesting access from the sponsor to the raw data (patient-level anonymised data or equivalent patient-level data). If this request has **not** been made please confirm "no request for raw data from the sponsor was made"

We can confirm that the clinical trials were performed in accordance with Good Clinical Practice (GCP) and that the sponsor had access to the raw data (patient-level anonymised data or equivalent patient-level data).

2. Confirmation as to whether the MHRA holds the patient-level data (approximately 70,000 records) from these applications or whether these were restricted from access or assessment by the sponsor. If they were supplied, please describe the format in which these records were supplied and how they were hosted at the MHRA (e.g. paper, or electronic database – specify format such as MySQL, MsSQL databases, csv, excel files)

We can confirm that the MHRA is permitted access to any pertinent raw data (patient-level anonymised data or equivalent patient-level data). Raw data may be held in different formats and are usually supplied to the MHRA electronically, but on rare occasions this could be via hard copy.

3. Any documents confirming that a process for analysing the raw data from the sponsor was undertaken, and the result of that process (e.g. meeting minutes or equivalent) including the qualifications (and names if appropriate) of the committee (if any) which has undertaken the review of the raw data. If no such committee review has taken place, please state "no committee review of the raw data has taken place"

We can confirm that the clinical trial data were analysed as they would be for any marketing authorisation application for a new medicinal product.

There were numerous internal meetings between MHRA staff, as well as between MHRA and the Vaccines Benefit Risk Expert Working Group (VBR EWG), and MHRA and Commission on Human Medicines (CHM). Names of MHRA staff are withheld under Section 40 (Personal Information) and Section 35 (Health and Safety) of the Freedom of Information (FOI) Act. Names and professional qualifications of the VBR EWG and CHM are available at: Membership - Commission on Human Medicines - GOV.UK (www.gov.uk) Summary minutes are also available within this page.

To provide a fuller answer to this question exceeds the FOI time limit of 24 working hours and so would be exempt under Section 12 (Unnecessary use of resources) of the FOI Act. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information. As your current request exceeds this limit, we will not be processing this part of your request any further.

We hope that as these vaccines have now been approved by many regulatory agencies around the world this should reassure you that a thorough assessment of the clinical trial data has been performed.

Regarding the MHRA approval of the Pfizer/BioNTech and the Oxford/AstraZeneca COVID-19 vaccines, further information (including information for physicians and recipients of the vaccine, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

Please note that a marketing authorisation was granted for the Pfizer/BioNTech vaccine (Comirnaty) following a European Commission (EC) decision on 21 December 2020 (PLGB 53632/0002). Further information is available on the European Medicines Agency (EMA) website, a link to this is provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

In addition, the European Commission, following recommendations from the European Medicines Agency (EMA), have granted a marketing authorisation for the Oxford/AstraZeneca vaccine. Further information is provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca

If you have a query about the information provided, please reply to this email

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 you receive this response and addressed to: info@mhra.gov.uk

Due to the ongoing Covid-19 situation, we are not able to accept delivery of any documents or correspondence by post or courier to any of our offices

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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

Yours sincerely

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
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