FOI 23/150 - Pfizer BNT162b2 conditions of authorisation

REQUEST
16 February 2023

Please could you confirm whether Pfizer Vaccine BNT162b2 complied with the CONDITIONS OF AUTHORISATION UNDER REGULATION 174 in full?
Yes or no.

Please provide evidence that each of the requirements outlined in this document https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-pfizer-biontech-vaccine-for-covid-19%2Fconditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine&data=05%7C01%7CBen.Scott%40mhra.gov.uk%7Cd83319664313463cb83c08db5d25932c%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638206188179219189%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=3sr1OkSuCi%2BUcDGB0qvzbqmXfREMl3a%2BoTsuj8ZwkvA%3D&reserved=0 was compiled with.

MHRA RESPONSE
25 May 2023

Thank you for your request under the Freedom of Information Act, we apologise for the delay in response.

We have reviewed your request and consider that Section 12 of the Freedom of Information Act applies. Section 12 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 £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information (which we consider applies to your second question, given the list on the website page (linked to below) runs to over 40 items).

In order for us to proceed we kindly ask for you to specify which of the conditions listed on the below webpage you would like us to provide evidence for:

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine

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

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 Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

FURTHER INFORMATION
30 November 2023

ICO decision notice issued:
https://ico.org.uk/media/action-weve-taken/decision-notices/2023/4027614/ic-254831-s5n2.pdf