

**FOI 23/616**

Dear

Thank you for your email.

*Can you please answer the following question with either a yes or no answer:*

*Has Pfizer/BioNtech complied with all the conditions of authorisation under Regulation 174 listed in [this](#) document?*

*For the avoidance of doubt the document I am referring to is:*

<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine#clinical-and-pharmacovigilance>

The MHRA considers that Pfizer/BioNtech have adequately complied with the Regulation 174 Conditions that fall within the MHRA's remit. A similar parliamentary question has been answered by Mr Neil O'Brien, Parliamentary Under Secretary in the Department of Health and Social Care, on November 22<sup>nd</sup> 2022 referring to the post-authorisation conditions that relate to the conditional marketing authorisations of the Comirnaty products (Pfizer / BioNtech Covid-19 vaccines) - see: <https://questions-statements.parliament.uk/written-questions/detail/2022-11-16/88800>.

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](mailto:info@mhra.gov.uk)

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

Please find below the Information Commissioner Office guidance on how to make a request for information

<https://ico.org.uk/for-the-public/official-information/how-to-write-an-effective-request-for-information/>

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

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