Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00807**

19 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 22 July. You wrote:

> *Thank you for acknowledging my request under reference FOI2026/00804.*
>
> *I am writing promptly because the scope reproduced in your acknowledgement differs materially from the request I submitted. To avoid unnecessary searches and any risk of exceeding the cost limit, please treat the following as a clarification of the original request, not as a new or expanded request.*
>
> *The relevant date range is:*
>
> *25 December 2020 to 10 January 2021 inclusive.*
>
> *I request only recorded information documenting the nature, scope, or form of the "MHRA agreement" referred to in the UK COVID-19 Technical Report, Chapter 9, in connection with the JCVI recommendation that the interval between doses of BNT162b2 could extend to 12 weeks.*
>
> *Specifically, I request:*
>
> *1. Any formal agreement, memorandum, written confirmation, decision record, or meeting record provided by or recording the position of MHRA concerning the acceptability of a programme interval of up to 12 weeks for BNT162b2.*
>
> *2. Any record explaining whether the wording "at least 21 days" in MHRA's updated advice and applicable product information was understood by MHRA as permitting a programme interval of up to 12 weeks, or whether it stated only a minimum interval without affirmatively endorsing that particular upper interval.*
>
> *For the avoidance of doubt:*
>
> *- I am not requesting general correspondence with Pfizer/BioNTech.*
> *- I am not requesting all communications concerning dose spacing.*
> *- I am not requesting a general search for legal opinions.*
> *- I am not asking about a Conditional Marketing Authorization unless a record within the narrow scope above specifically relies on one.*

- Duplicate records, routine administrative correspondence, and press-monitoring material remain excluded.

Please confirm that the request will be processed using this clarified scope. If any further refinement would assist disclosure under section 16 of the Freedom of Information Act 2000, I would be happy to discuss it.

MHRA Response

We confirm that we hold the information you have requested.

1. *Any formal agreement, memorandum, written confirmation, decision record, or meeting record provided by or recording the position of MHRA concerning the acceptability of a programme interval of up to 12 weeks for BNT162b2.*

Our response:
Under Section 1(1) (a) of this information is not held. Refer to answer below; 'at least 21 days apart' without specifying an upper interval was set out for the Covid-19 Pfizer/BioNTech Vaccine (BNT162b2).

2. *Any record explaining whether the wording "at least 21 days" in MHRA's updated advice and applicable product information was understood by MHRA as permitting a programme interval of up to 12 weeks, or whether it stated only a minimum interval without affirmatively endorsing that particular upper interval.*

Our response:
We can confirm that the Agency holds this information; the answer is the latter i.e. product information and advice explained '*only a minimum interval without affirmatively endorsing that particular upper interval*'.

However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain. Please see the below excerpt from the Covid-19 vaccine benefit-risk EWG of 31 December 2020. While some of the below content relates to Moderna there are mentions of the Covid-19 Pfizer/BioNTech Vaccine (BNT162b2), see section 2.4, line 11:

> dose on day 29. In accordance with the product information for Pfizer/BioNTech (BNT162b2) the second dose is to be given at least 21 days after first dose. The product information for

Source: Covid-19 Vaccines Benefit Risk Expert Working Group meeting of Thursday 31st December 2020
https://assets.publishing.service.gov.uk/media/67a51b794dd52dddeb16a87c/31_December_2020.pdf

Please note, the above should be read in conjunction with the information from the vaccine benefit-risk Covid-19 EWG minutes available online, where for the Covid-19 Pfizer/BioNTech Vaccine (BNT162b2) a dose interval of 'at least 21 days apart' without specifying an upper bound was set out, see item 6.7. Note, this particular set of minutes fell outside the time period specified in your request and so is provided as 'advice and assistance'.

6.7	The EWG heard that the ever-changing public health need can be taken into consideration when making a decision. The EWG agreed that the dosing recommendation should be 'at least 21 days apart' without specifying an upper bound. The EWG noted this is also in line with the EMA recommendation.

Source: Covid-19 Vaccines Benefit Risk Expert Working Group meeting of Thursday 24th December 2020.

https://assets.publishing.service.gov.uk/media/67a51b798259d52732f6ae2c/24_December_2020.pdf

Further advice and assistance:

As is mentioned above the expert group concluded that vaccine efficacy will be maintained with dosing intervals longer than 21 days, as specified in the Information for Healthcare Professionals document. This was in line with the Conditional Marketing Authorisation issued to Pfizer/BioNTech by the European Medicines Agency on 21 December.

The below publication by the JCVI may also be of interest to you:
Optimising the COVID-19 vaccination programme for maximum short-term impact - GOV.UK

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/