



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](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00950**

23 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 25 August. You wrote:

Dear MHRA FOI Team,

Thank you for your response to FOI2026/00830 and for your section 16 advice.

I submit this as a new, refined request. It is limited to the three questions your response identified as likely capable of processing within the appropriate limit.

Please provide the following recorded information:

- 1. The date on which MHRA received the final report of the developmental and reproductive toxicity study for Comirnaty, and the date of each interim DART dataset or report received before the final report.*
- 2. For each of the following decisions, state the procedure under which the decision was made and the decision date:*
 - a. the Regulation 174 temporary authorisation of the Pfizer/BioNTech vaccine;*
 - b. the full marketing authorisation for Comirnaty; and*
 - c. the authorisation of Comirnaty for infants and children aged 6 months to 4 years.*
- 3. Identify the role or post responsible for signing off an authorisation under the reliance route, and the criteria against which that decision is taken.*

I am not seeking a general email search, personal data, or all underlying documents at this stage. If any item is not held, please confirm that under section 1(1)(a).

MHRA Response

The Agency has completed its search for the information you have requested and we are able to confirm that we do hold the information you have requested. Please find the answers to each of your questions below:

1. The date on which MHRA received the final report of the developmental and reproductive toxicity study for Comirnaty, and the date of each interim DART dataset or report received before the final report.

We have taken your question to relate to the original Pfizer/BioNTech Covid-19 vaccine.

A summary of results from "A Combined Fertility and Developmental Study (Including Teratogenicity and Postnatal Investigations) of BNT162b1, BNT162b2 and

BNT162b3 by Intramuscular Administration in the Wistar Han Rat” was received by the MHRA on 22 December 2020.

The final study report for this study was received by the MHRA on 05 January 2021.

2. For each of the following decisions, state the procedure under which the decision was made and the decision date:

a. the Regulation 174 temporary authorisation of the Pfizer/BioNTech vaccine;

b. the full marketing authorisation for Comirnaty; and

c. the authorisation of Comirnaty for infants and children aged 6 months to 4 years.

The Regulation 174 authorisation for the Pfizer/BioNTech Covid-19 vaccine was granted on 02 December 2020. The application was submitted via the rolling review route.

You may be interested in the below:

[Regulations 174A and 247A: one-year review - GOV.UK](#)

Public Assessment Report for the regulation 174 authorisation:

[Public Assessment Report](#)

A Conditional Marketing Authorisation (CMA) was granted for the Pfizer/BioNTech vaccine (Comirnaty) following a European Commission (EC) decision on 21 December 2020.

<https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty>

Further information about CMAs can be found at the link below:

[Conditional marketing authorisation | European Medicines Agency \(EMA\)](#)

Following the UK's departure from the European Union (EU), this centralised authorisation was automatically converted to a Great Britain (GB) Marketing Authorisation on 01 January 2021 (PLGB 53632/0002). On 09 November 2022, the status was changed from a CMA to a standard Marketing Authorisation.

Comirnaty 3 micrograms/dose Concentrate for dispersion for injection (PLGB 53632/0008) was authorised for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years on 05 December 2022. This Marketing Authorisation was granted via the EC Decision Reliance procedure. In coming to its decision MHRA relied on an EC decision on 20 October 2022 (EMA/H/C/005735/X/0138).

The EMA and MHRA Public Assessment Reports can be accessed via the links below:

[Comirnaty, INN-tozinameran, tozinameran/riltozinameran](#)

[4be8e89c9460839c2f6e291b9f32d9e2ccd5c5f5](#)

3. Identify the role or post responsible for signing off an authorisation under the reliance route, and the criteria against which that decision is taken.

There is no single role or post responsible for signing off an authorisation under the EC Decision Reliance Route.

Please note that the reliance routes (EC and mutual recognition/decentralised) were incorporated into the new MHRA International Recognition Procedure (IRP) as of 01 January 2024. Further information about the IRP route of application is available below:

[International Recognition Procedure - GOV.UK](#)

IRP allows the MHRA to take into account the expertise and decision-making of trusted regulatory partners for the benefit of UK patients. MHRA still retains the authority to approve

or refuse applications if the scientific evidence provided by the applicant is considered insufficiently robust. When an IRP application is received, it is triaged and assessors are assigned accordingly, as required. Therefore, the assessment of an application and the subsequent decision as to whether it is approved varies by application. The assessment of an IRP application may involve several different assessors within the HealthCare Quality & Access and Safety & Surveillance Teams within MHRA.

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.

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>