



Medicines & Healthcare products Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/01083**

1 October 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 3 September. You wrote:

I am requesting documentation indicating when MHRA first received trial data from Astra Zeneca, Moderna and Pfizer about its Covid-19 vaccine and for how many weeks and months afterwards continuing trial data was received by MHRA prior to authorisation of the vaccine for general use

MHRA Response

Introduction

We apologise for the delay in replying to your letter, unfortunately your physical letter was missed amongst other postal deliveries, and noted for triage later than it should have been. We are also in the process of drafting a response to your other FoI request **FOI2026/01081**.

The Covid-19 vaccines were first given temporary authorisation under regulation 174*. We have interpreted your request to relate to the packages of clinical data used to support the Regulation 174 authorisations. Please note, ahead of licensing activities, MHRA would have also received data from clinical trials conducted in the UK which went on to inform the submission packages. Furthermore, there may have been scientific advice meetings, and pre-submission meetings which may have included snapshots of clinical data ahead of the submissions. The publicly available minutes and the public assessment reports provide a good overall picture of the types of data submitted and reviewed.

The [Moderna COVID-19 vaccine](#) was also authorised under R174 (and subject to conditions under R174A) on 8 January 2021, however no Moderna supply was provided under R174A. [Regulations 174A and 247A: one-year review - GOV.UK](#)

We confirm that we hold the information you have requested and provide it below:

AstraZeneca (COVID-19 Vaccine (ChAdOx1-S [recombinant]), 1 x 10 (11)

vp/mL, solution for injection).

According to our records, the first package of clinical data was submitted on 5th December 2020, the last package of clinical data was received on 23rd December 2020. The temporary authorisation of this vaccine occurred under regulation 174 on 30th December 2020. Please note, that we cannot rule out the possibility that smaller packages of clinical data were provided in the short window between 23rd December and 30th December 2020.

Moderna Covid-19 Vaccine mRNA-1273

The first package of clinical data was submitted on 29th October 2020 the last package of clinical data was received on 11th December 2020. The temporary authorisation of this vaccine occurred under regulation 174 on 8th January 2021, but supply under R.174 did not occur.

Pfizer

The first package of clinical data was submitted on 7th October 2020 the last package of clinical data was received on 23rd November 2020. The temporary authorisation of this vaccine occurred under regulation 174 on 2nd December 2020. Please note, that we cannot rule out the possibility that smaller packages of clinical data were provided in the short window between 23rd November 2020 and 30th December 2020.

Advice and assistance

Please note, it has been difficult to ascertain from our records if any differences existed between the date of a letter or document, the sources which we the dates on which populate the response above e.g. a cover letter stating that a clinical package has been provided and the effective date when that package arrived. However, we expect any difference between submitted and received dates to be marginal / non-consequential. We also cannot rule-out small packages of data particularly in relation to the documents approaching authorisation being submitted by email. However, we would expect such documents to relate to minor text amendments to product information, where an assessor may be discussing wording with the stakeholder, rather than concerning clinical data.

Please also note, the time difference between the two dates should not be regarded as how long each vaccine was studied for, rather, it relates to the interpretation of the trial data.

Safety and efficacy of the Covid-19 vaccines

The MHRA approved each Covid-19 vaccine based on a rigorous assessment of their safety, quality and efficacy. The MHRA is globally recognised for requiring high standards of safety and all Covid-19 vaccines were only authorised following a careful evaluation of the data. Throughout the assessment process the MHRA sought the expert advice of the independent Commission on Human Medicines (CHM) and their expert committees.

The MHRA employs a comprehensive approach to benefit risk assessments, which includes a structured methodology that follows international guidance, incorporating scientific evaluation, independent expert advice, and robust post-authorisation surveillance. The post-approval assessment process includes access to epidemiological expertise in the evaluation of real-world data and special considerations for the needs of vulnerable populations.

As part of its statutory functions, the MHRA is responsible for continuously monitoring all vaccines post-authorisation to ensure their benefits continue to outweigh any risks. As with all other medicines, the Covid-19 vaccines are subject to the MHRA's safety monitoring strategy to identify safety issues. This monitoring strategy is continuous, proactive and based on a wide range of information sources, with a dedicated team of scientists reviewing information daily to look for safety issues or unexpected, rare events. The MHRA's ongoing vigilance

helps to ensure that the benefits of approved products consistently outweigh any potential risks, thereby safeguarding public health.

No vaccine is completely without risk. All vaccines and medicines have the potential to cause side effects, and these are outlined in the product information for each medicine, including the Patient Information Leaflet. These side effects need to be continuously balanced against the expected benefits in preventing illness at a population level.

As demonstrated by data from the UK Health Security Agency (UKHSA), vaccination remains the most effective way to reduce deaths and severe illness from Covid-19. Further, following administration of over 100 million doses of Covid-19 vaccines in the UK alone since December 2020, there is a considerable amount of real-world effectiveness and safety data available to complement the data from clinical trials. The benefits of the vaccines in preventing Covid-19 and serious complications associated with Covid-19 far outweigh any currently known side effects in the majority of patients.

As with all vaccines and medicines, the safety of Covid-19 vaccines is continuously monitored, and benefits and possible risks remain under review. Please be assured that should any new safety issue be confirmed, the MHRA will continue to act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk.

I hope this information is helpful. Please do contact us if you have any further questions.

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/>