Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00524**

12 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 14 May. You wrote:

> *I have concerns about the rollout of the COVID jabs of 2020. Please see this as a FOIA request.*
>
> *In particular I wish to see the contemporary evidence bases on which you relied to state, on numerous occasions, that the COVID jabs were safe and effective.*
>
> *The vaccine rollout started in Dec 2020 following initial clinical trials*
>
> *Please supply the evidence base available to you and on which you relied at that time to assert that the vaccines were safe*
> *Please supply the evidence base available to you and on which you relied at that time to assert that the vaccines were effective.*
> *I wish to see the actual studies and the actual raw data to support your assertions.*

MHRA Response

The Medicines and Healthcare products Regulatory Agency (MHRA) can confirm that it does hold the relevant information requested, but that this request is extremely broad. As such, we consider that section 12 of the FOIA applies. This is because the time needed to undertake the activities of determining all information within the scope of your request, and locating, retrieving and extracting that information exceeds the 24-hour 'appropriate limit' set out in the FOI Act.

We consider that the scope of this question would include all relevant information relating to this subject which would be held throughout the lifecycle of the marketing authorisations of each of the COVID-19 vaccines to the present time. This would require retrieval of 1000s of pages of information and reports held in multiple different locations within the MHRA. To explain this, we've included a link to the Information Commissioner's decision on a similar type of request which also required the retrieval of evidence from multiple areas of the MHRA [https://ico.org.uk/media/action-weve-taken/decision-notices/2023/4027614/ic-254831-s5n2.pdf].

Although we are applying a section 12 exemption to this request, we would like to provide advice below to assist you in making a new narrowed request; we hope this is useful in

explaining the scope of the information that you have asked about and may assist you in identifying a specific topic that you may wish to focus a request on.
All vaccines used in the UK are authorised by the Medicines and Healthcare products Regulatory Agency (MHRA). Each COVID-19 vaccine is only authorised once it has met robust standards of effectiveness, safety, and quality. Public Assessment Reports on data from clinical trials showing the efficacy and safety of the COVID-19 vaccines which were submitted for their authorisation are accessible on the MHRA's product website, accessible via the following link: MHRA Products | Home

Details of batch testing undertaken by NIBSC is available here. This webpage provides further links to the NIBSC website: https://www.gov.uk/government/news/independent-batch-release-testing-of-covid-19-coronavirus vaccines-by-the-nibsc Data from clinical trials showing the efficacy and safety of the Covid vaccines which were submitted for their authorisation are available through the Public Assessment Reports (PARs) published by MHRA and the European Medicines Agency (EMA). Links to these for Comirnaty (Pfizer vaccines), Vaxzevria (AstraZeneca vaccines) and Spikevax (Moderna vaccines) are provided below:

https://products.mhra.gov.uk/search/?search=spikevax&page=1&doc=Par&rerouteType=0

https://products.mhra.gov.uk/search/?search=comirnaty&page=1&doc=Par&rerouteType=0

https://products.mhra.gov.uk/search/?search=Vaxzevria&page=1&doc=Par&rerouteType=0

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

https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna

https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca

Further, data from these clinical trials are publicly available through the EMA Clinical Repository, a link to this is provided below: https://clinicaldata.ema.europa.eu/web/cdp/home

As with all vaccines and medicines, the safety of COVID-19 vaccines is continuously monitored, and the advice from the MHRA remains that the benefits of vaccination in preventing COVID-19 and serious complications associated with COVID-19 outweigh any currently known side effects in the majority of patients. Information on the characteristics of each vaccine is published by the MHRA on the GOV.UK website. Between February 2021 and March 2023 the MHRA regularly published the summary of Yellow Card reporting for COVID-19 vaccines, which provides an overview of the MHRA's safety assessments concerning these products along with the numbers and types of all UK suspected adverse reaction reports we have received for the COVID-19 vaccines, including other relevant information from other studies.

The MHRA sought independent advice from the Commission on Human Medicine (CHM) and their Expert Advisory Group on COVID-19 vaccines on specific safety issues. Summary minutes from CHM meetings can be available at Membership - Commission on Human Medicines - GOV.UK (www.gov.uk) and the CHM Annual Reports for 2021 and 2022 are available here: https://www.gov.uk/government/organisations/commission-on-human-medicines

Periodic safety update reports (PSURs) are pharmacovigilance documents submitted by Marketing Authorisation Holders (MAHs) at defined time points during the post-authorisation

phase. The main objective of a PSUR is to present a comprehensive, concise and critical analysis of the risk-benefit balance of the medicinal product taking into account new or emerging information in the context of cumulative information on risks and benefits. For further information about PSURs, please see the Guideline on good pharmacovigilance practices (GVP): Guideline on good pharmacovigilance practices (GVP) Module VII – Periodic safety update report (Rev 1)

PSURs for COVID-19 vaccines are published by the European Medicines Agency (EMA) under the 'Safety updates' sections of the following links:

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

https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca

https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna

Further, you may also be interested in the International Coalition of Medicines Regulatory Authorities (ICMRA), which includes the MHRA, statement on the safety of COVID-19 vaccines which includes a section of evidence of COVID-19 vaccine safety after use of billions of doses:

ICMRA statement on the safety of COVID-19 vaccines | International Coalition of Medicines Regulatory Authorities (ICMRA)

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