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: **FOI2026/00615**

2 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 8 June. You wrote:

> *I write to make a request under the Freedom of Information Act 2000.*
>
> *Background*
>
> *In December 2025, the United States Food and Drug Administration's (FDA) Office of Biostatistics and Pharmacovigilance completed a structured case-level causality review of 96 paediatric death reports submitted to the Vaccine Adverse Event Reporting System following COVID-19 vaccination. That review applied the World Health Organization (WHO)–Uppsala Monitoring Centre (UMC) causality assessment framework to each individual case, drawing on medical records, autopsy reports, pathology findings, and follow-up information. The findings were released into the public domain via a United States Senate disclosure in May 2026, and their authenticity has been confirmed by an HHS official.*
>
> *I am conducting independent research into comparative post-market pharmacovigilance practice across medicines regulators, with particular reference to the MHRA, FDA, and European Medicines Agency. The MHRA's statutory obligation to conduct rigorous benefit-risk assessment of authorised medicinal products, and to disclose the basis and limitations of that assessment, provides the domestic regulatory standard against which the question raised by this request is framed.*
>
> *Duty to Confirm or Deny*
>
> *If the MHRA does not hold any of the information requested below, I ask that you confirm that position in writing, as the absence of an equivalent structured review is itself material to comparative research in this area.*
>
> *Information Requested*
>
> *1. Whether the MHRA has conducted, or commissioned, any structured case-level causality review of Yellow Card fatal outcome reports in individuals aged under 18 years following COVID-19 vaccination, applying a recognised causality assessment framework (such as the WHO-UMC framework or equivalent).*

2. If such a review has been conducted: (a) the date or date range of the review; (b) the total number of Yellow Card fatal outcome reports reviewed; (c) the causality classifications assigned, expressed by category (certain, probable/likely, possible, unlikely, unassessable or equivalent); (d) the vaccine products and, where available, the age range of cases reviewed; and (e) whether the review has been published or is otherwise in the public domain, and if so, where.

3. If no such structured review has been conducted: whether the MHRA has assessed paediatric fatal outcome reports following COVID-19 vaccination by any other systematic methodology, and if so, what that methodology was and what its outputs were.

Clarification

I am not requesting the underlying individual case records. I am requesting the existence and outputs of any structured aggregate causality review, and the methodology applied.

I look forward to your acknowledgement of this request and your response within the statutory 20 working days under the Freedom of Information Act 2000.

MHRA Response

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

1. Whether the MHRA has conducted, or commissioned, any structured case-level causality review of Yellow Card fatal outcome reports in individuals aged under 18 years following COVID-19 vaccination, applying a recognised causality assessment framework (such as the WHO-UMC framework or equivalent)
The MHRA has conducted 2 paediatric (individuals aged under 18 years) reviews that included fatal reports and all fatal reports were followed up. We always review case reports for causality but do not restrict to frameworks and each case is reviewed individually.
We established the Yellow Card Vaccine Monitor (YCVM) to facilitate active monitoring of adverse drug reactions following COVID-19 vaccinations and further characterise safety in populations under-represented in clinical trials. This study explored the profile of individuals registered to the YCVM platform and the suspected adverse drug reactions reported following a COVID-19 vaccination on this data platform. You can find this information here: Implementation and Results of Active Vaccine Safety Monitoring During the COVID-19 Pandemic in the UK: A Regulatory Perspective - PMC

2. If such a review has been conducted:
(a) the date or date range of the review;
(b) the total number of Yellow Card fatal outcome reports reviewed;
(c) the causality classifications assigned, expressed by category (certain, probable/likely, possible, unlikely, unassessable or equivalent);
(d) the vaccine products and, where available, the age range of cases reviewed; and
(e) whether the review has been published or is otherwise in the public domain, and if so, where.

The MHRA does not hold a framework-based causality clarification table or report of the type requested.

3. If no such structured review has been conducted: whether the MHRA has assessed paediatric fatal outcome reports following COVID-19 vaccination by any other systematic methodology, and if so, what that methodology was and what its outputs were.

We do not restrict strictly to frameworks, and each case is reviewed individually. We do apply the general principles from frameworks relevant to assessing causality, which includes considering temporality of the association, biological plausibility and any alternative explanation. Some individual cases are also taken to committees for expert advice. There was a total of 15 fatal reports.
The MHRA's pharmacovigilance approach relies on continuous assessment of Yellow Card reports, follow-up investigations, expert review and signal detection rather than causality assessment frameworks.
The UK Covid-19 Inquiry Module 4: Vaccines and therapeutics described the MHRA's post-authorisation safety monitoring. This includes our robust systems and strategies, monitoring for Covid-19 vaccines, the effectiveness of the Yellow Card scheme, obligations on pharmaceutical companies and responding to safety concerns. You can find this information here: Module 4: Vaccines and therapeutics - UK Covid-19 Inquiry

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/