Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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London
E14 4PU

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MHRA Website

Our Ref: **FOI2026/00871**

3 September 2026

Dear [redacted]

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

> *Batch Product Date*
> *administered*
> *E5019 Diphtheria, tetanus, pertussis (triple)*
> *with polio*
> *11 January 1996*
> *E5019 Diphtheria, tetanus, pertussis (triple)*
> *with polio*
> *13 February 1996*
> *E5015 Diphtheria, tetanus, pertussis (triple)*
> *with polio*
> *26 March 1996*
> *HB15350 Measles, mumps and rubella (MMR) 31 December 1996*
> *HJ11120 Measles, mumps and rubella (MMR),*
> *booster*
> *27 March 2000*
> *N1156-51*
> *S125PP*
> *Diphtheria/tetanus (double) with polio,*
> *booster*
> *27 March 2000*
> *2 | P a g e*
> *For each of the six batches listed above, please provide:*
> *1. The product name and the marketing authorisation holder or manufacturer.*
> *2. The UK batch release certification issued in respect of that batch, including any independent testing carried out by the National Institute for Biological Standards and Control, and the certificate of analysis or equivalent release documentation.*
> *3. Details of any out-of-specification, out-of-trend, or non-conforming test result recorded against that batch at any stage of release testing.*
> *4. Details of any quality defect investigation, manufacturer field alert, recall, quarantine, or Drug Alert notice issued in relation to that batch.*
> *5. The number of Yellow Card adverse reaction reports recorded against that batch number, broken down by reaction category.*

Additionally:
1. For batches E5019 and E5015 specifically, the thiomersal content per dose expressed in micrograms of ethylmercury, together with the specification range for that product at the time of release.
2. For the Haemophilus influenzae type b (Hib) vaccine in routine NHS use in England between January and March 1996: the product name, the marketing authorisation holder, and the thiomersal content per dose.
3. Any quality defect investigation, recall, or Drug Alert notice issued in respect of any DTwP or Hib batch distributed in England between January and June 1996.

MHRA Response

We can neither confirm nor deny we hold information falling within the description specified in your request under section 12(2) of the Freedom of Information Act, as to do so would exceed the cost limit.

This is because we estimate the cost of checking if we hold the requested information or not would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(2) of the FoI Act the Agency is not therefore obliged to comply with your request and we will not be processing it further. The reason being we have established that input would be required from at least three operating groups to process your request and with searches across a range of teams. Our preliminary searches have also identified a need to search records stored off-site in a paper archive and this is estimated to greatly increase the time required to complete searches to far beyond the 24 hour limit.

Under Section 16 of the FoI Act we should help you narrow your request so that it may fall beneath the cost limit. We suggest refining your request:

- to a single vaccine with specific details pertaining to the brand name and or batch number and expiry date information, for a vaccine administered in 2000 (later records carry less likelihood of needing to search the off-site paper archive).

  and

- *to narrow the request to question 5. 'The number of Yellow Card adverse reaction reports recorded against that batch number, broken down by reaction category'.*

Before submitting a new request, please ask for the vaccine product name and PL number from your GP; these details will help guide searches of our records.

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 Contact Information or telephone 0303 123 1113.

Re-use of our information
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/