Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2024/00820**

17 January 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 22 December 2024. You wrote:

> *Please could you provide me with copies of all of the placebo-controlled trials considered as part of the authorisation process for each of the current vaccines in the recommended childhood vaccine schedule?*
>
> *I'd like to receive these via pdf or word document via email to this address.*

MHRA Response

We can confirm that the Agency holds this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

We have provided a list below of the vaccines required up to 1 year, as stated in the NHS Vaccination Schedule (NHS vaccinations and when to have them - NHS). Next to each vaccine we have provided the link to the Public Assessment Report (PAR) for that vaccine that has been published by either the European Medicines Agency (EMA) or by MHRA. These PARs detail the assessment of the clinical studies required for the grant of these vaccines. For the measles, mumps and rubella (MMR) vaccine Priorix powder and solvent for solution for injection (PL 10592/0110), we have provided the MHRA assessment report for this vaccine (as there is no PAR published for this vaccine).

8 weeks
6-in-1 vaccine - Infanrix Hexa | European Medicines Agency (EMA)
Rotavirus vaccine - Rotarix | European Medicines Agency (EMA)
MenB vaccine - Bexsero | European Medicines Agency (EMA)

12 weeks
6-in-1 vaccine (2nd dose)
Pneumococcal vaccine - Prevenar 13 | European Medicines Agency (EMA)
Rotavirus vaccine (2nd dose)

16 weeks
6-in-1 vaccine (3rd dose)

MenB vaccine (2nd dose)

1 year
Hib/MenC vaccine (1st dose) - Microsoft Word - DCPAR for Menitorix FINAL
MMR vaccine (1st dose) – We attach the MHRA assessment report for the vaccine Priorix powder and solvent for solution for injection (PL 10592/0110), which was authorised by MHRA on 04 December 1997.
Pneumococcal vaccine (2nd dose)
MenB vaccine (3rd dose)

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