FOI 23/650

Dear

Thank you for your email.

> *"Please can you send me copies of the following documents (electronic copies preferred):*
>
> *The study showing the efficacy of Infanrix hexa in infants.*
> *The study showing the safety of Infanrix hexa in infants (if different from the above study).*
>
> *The study showing the efficacy of Vaxelis in infants.*
> *The study showing the safety of Vaxelis in infants (if different from the above study).*
>
> *The study showing the efficacy of Bexsero in infants.*
> *The study showing the safety of Bexsero in infants (if different from the above study).*
>
> *The study showing the efficacy of Rotarix in infants.*
> *The study showing the safety of Rotarix in infants (if different from the above study).*
>
> *The study showing the efficacy of the combined administration of Infanrix hexa / Vaxelis, Bexsero and Rotarix in infants.*
> *The study showing the safety of the combined administration of Infanrix hexa / Vaxelis, Bexsero and Rotarix in infants (if different from the above study)."*

Information on the efficacy of these vaccines is available from the European Medicines Agency PARs, links to which have been provided beneath each request for a specific product:

The study showing the efficacy of Infanrix hexa in infants.
The study showing the safety of Infanrix hexa in infants (if different from the above study).
https://www.ema.europa.eu/en/medicines/human/EPAR/infanrix-hexa

The study showing the efficacy of Vaxelis in infants.
The study showing the safety of Vaxelis in infants (if different from the above study).
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxelis

The study showing the efficacy of Bexsero in infants.
The study showing the safety of Bexsero in infants (if different from the above study).
https://www.ema.europa.eu/en/medicines/human/EPAR/bexsero

The study showing the efficacy of Rotarix in infants.
The study showing the safety of Rotarix in infants (if different from the above study).

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

The study showing the efficacy of the combined administration of Infanrix hexa / Vaxelis, Bexsero and Rotarix in infants.
The study showing the safety of the combined administration of Infanrix hexa / Vaxelis, Bexsero and Rotarix in infants (if different from the above study).
If the information is not available through the above links to the EMA PARs, information on the use of multiple vaccines in infants is available through NICE, a link to this information is provided below:
https://cks.nice.org.uk/topics/immunizations-childhood/

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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