FOI 23/142

REQUEST

18 February 2023

I would like to request the clinical trial safety data for the Glaxosmith Klein Infranix hexa 6 in 1 vaccine given to new born babies and Vaxelis 6 in 1 vaccine also given to new born babies.

I've searched through your website, the NHS website and the manufacturers website, but cannot find anything related to clinical trials, could you let me know if clinical trials were actually conducted and if so provide the raw data from those trials.

MHRA RESPONSE

Dear

Thank you for your email.

Infanrix Hexa Powder and Suspension for Suspension has been authorised by MHRA (PLGB 19494/0261). It was authorised on 23 October 2000, following a centralised procedure. Further information, including the Public Assessment Report, is available from the EMA, link provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/infanrix-hexa

The request for all the raw clinical data is refused under Section 12 of the FOIA (unreasonable use of resources). The link above provides information on the clinical studies submitted and the assessment by the EMA of these data for the authorisation of this medicinal product. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information and to amalgamate with this one would take us over 24 working hours.

We ask that you refine any further request to one particular study you are interested in receiving information for.

In regards to whether any trials for Infanrix Hexa 6 in 1 and Vaxelis 6 in 1 were conducted in the UK we can confirm that there is one trial for ‘Infanrix Hexa’ or ‘Vaxelis’ being investigated with new-born babies, conducted by GSK and one other trial with using these products with infant and toddlers.

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
Medicines and Healthcare products Regulatory Agency
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