Medicines & Healthcare products
Regulatory Agency

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Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

15th November 2023

FOI 23/787

Dear [redacted]

Thank you for your information request, dated 18.10.2023**,** where you asked for:

"I am writing to you under the Freedom of Information Act 2000 to request the following information from MHRA.

My request concerns MRHA approval of clinical trials in pregnant people.

Please may you provide me with the Reproductive Toxicology Guidelines (including the requirements for preclinical trials in pregnant animals and Phase 1 studies in pregnant humans) covering preterm births, intrauterine growth retardation (small for dates babies), and guidelines covering the development of pre-eclampsia and other pregnancy-related conditions affecting the pregnant person."

Section 21 – Information accessible by other means: the information you have requested is already in the public domain.

Reproductive Toxicology Guidelines and all other scientific guidelines applicable to the assessment of clinical trials, including pregnant individuals, are available in the public domain and can be found at:

https://www.ich.org/page/ich-guidelines

https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines

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The Act's section 21 exemption states that there is no right of access to information via FOI if it is reasonably available to the applicant by another route.

If you have a query about the information provided, please reply to this email.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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,
Clinical Investigations and Trials
(Science, Research and Innovation Group)