FOI 23/658

Dear

Thank you for your email.

Information on Topiramate in Pregnancy

we would like to ask what

- I. Communication
- II. Information
- III. Instructions
- IV. The date any on the above began

On the knowledge of the dangers of Topiramate in pregnancy with the MHRA and/or the Commission for Human Medicines.

We are happy to provide you this information that is available on the following link of the website below.

<u>Safety review to begin on topiramate - GOV.UK (www.gov.uk)</u> <u>Topiramate (Topamax): start of safety review triggered by a study reporting an</u> <u>increased risk of neurodevelopmental disabilities in children with prenatal exposure -</u> <u>GOV.UK (www.gov.uk)</u>

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