Medicines & Healthcare products
Regulatory Agency

[redacted]

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

17 March 2023

FOI **22/1213**

Dear [redacted]

Thank you for your information request, dated 20 December 2022, where you asked for copies of:

1. Minutes and papers of all meetings relating to the consideration of and decisions made relating to the CHM's new advice provided to the MHRA and the public including relevant minutes of the Sodium Valproate Expert Working Group, the Medicines for Women's Health Expert Advisory Group and the minutes of all relevant meetings of the CHM.

2. Any papers relating to the process that led up to the providing of the new advice to the MHRA and information on any advisory group involved including the named individuals in each group.

3. Any written record made of the views of individuals and stakeholders who have been contacted including any letters received.

4. Any data and research papers used, and any risk assessment and any equalities impact assessment done - to inform the change of advice

I apologise for the delay in responding to your query. Unfortunately, the information is exempt from release under:

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Section 22 – Information intended for future publication: the information you have requested is due to be published in the coming weeks. Section 22 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there is a general public benefit from publishing the scientific basis for regulatory decisions in order to promote understanding of the decisions taken. However, we consider that the public interest will be better served by not releasing the information in advance of the publication of the full package of information for healthcare professionals and patients.

Section 35 – Formulation of Government policy: the information you have requested is being withheld under section 35 of the FOI Act. Section 35 protects the internal deliberative process as it relates to Government policy making. In other words, the exemption is intended to ensure that the possibility of public exposure does not deter from full, candid and proper deliberation of policy formulation and development, including the exploration of all options, the keeping of detailed records and the taking of difficult decisions. Section 35 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there is a general public benefit from publishing the scientific basis for regulatory decisions in order to promote understanding of the decisions taken. However, we consider that the public interest will be better served by not releasing the information at the current time as to release information prematurely before the regulatory action is finalised could create confusion.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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

Medicines & Healthcare products
Regulatory Agency

Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

Safety and Surveillance