Medicines & Healthcare products
Regulatory Agency

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

[redacted]

13 September 2023

Dear [redacted]

FOI 23/489 Internal Review

I am writing in response to your request for a review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') reply to your FOI request (23/489).

The purpose of this review is to determine whether the Agency dealt properly and fairly with your request under the Freedom of Information Act (FOIA). In particular, it will examine the reasons why information was withheld from you.

Your original request and the Agency's response are annexed.

Consideration of the issues

You stated in your request for this review *'it is my view that in light of the significant delay in releasing the published guidance (expected early 2023) and the limited opportunity for charitable bodies and professional bodies to comment on the guidance before publication of the guidance that release of the requested information would overwhelmingly serve the public interest'.*

The MHRA response to FOI 23/489, dated 16 August 2023 explained that the information you requested was exempt from release under Section 22: Information intended for future publication and Section 35: Formulation of Government policy of the FOI Act.

Both Section 22 and Section 35 are qualified exemptions and the MHRA considered the public interest in disclosing the information:

Under Section 22, whilst it was considered that that there is a general public benefit from publishing the scientific basis for regulatory decisions in order to promote an understanding of the decisions taken, it was considered that the public interest would be better served by not releasing the information in advance of publication of the full package of information for both healthcare professionals and patients.

Under Section 35, which protects the internal deliberative process as it relates to Government Policy making, it was considered that it was not in the public interest to release the information at the current time as releasing the information prematurely before the regulatory action was finalised could create confusion.

Conclusions and recommendations

Following consideration of the response to your request, I conclude that the Agency has met its obligations and the exemptions were applied appropriately in not disclosing the requested information. In addition, I conclude that the Agency considered the public benefit of disclosure of the information requested and had been helpful in providing the reasoning for not doing so.

As the full package of information for healthcare professionals and patients is due to be published once regulatory action has concluded, it would not be in the public interest to release information ahead of this and prior to finalisation of the regulatory action. I therefore find that Agency's decision to not disclose the requested information ahead of publication appropriate as doing so could cause confusion and would not be in the public interest.

As you may be aware, the Agency has recently published an update on the review, in relation to a retrospective observational study on the risk to children born to men who took valproate in the 3 months before conception Valproate: re-analysis of study on risks in children of men taking valproate - GOV.UK (www.gov.uk). The communication highlighted the need for re-analysis of the data from this study before conclusions can be drawn.

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If you remain dissatisfied, you may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. The ICO's address is:

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

[redacted]

Safety and Surveillance
Medicines and Healthcare products Regulatory Agency