Medicines & Healthcare products
Regulatory Agency

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[redacted]

[redacted]

[redacted]

28 April 2023

FOI 23/227

Dear [redacted]

Thank you for your information request, dated 27 March 2023.

With reference to the below statement published in December 2022,

“The CHM has advised that no one under the age of 55 should be initiated on valproate unless two specialists independently consider and document that there is no other effective or tolerated treatment. Where possible, existing patients should be switched to another treatment unless two specialists independently consider and document that there is no other effective or tolerated treatment or the risks do not apply.”

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In your request you have asked for the reasons for the CHM and MHRA reaching the conclusion that an update was required.

You have also asked “why the CHM and MHRA feel it necessary to take it as far a ban on new prescriptions and for men and women up to the age of 55 years old.”

MHRA reply

We would like to clarify that the CHM review of 2022 which led to the recommendations was due to ongoing concerns about the effectiveness of the current measures to reduce the risks in women as well as concerns about the reproductive risks for males. The review was informed by input from patients and stakeholders on the adequacy of existing risk minimisation, the latest data from the Medicines and Pregnancy Register showing pregnancies continuing to be exposed despite the pregnancy prevention programme and an evolving data set of harms relating to male reproductive risks and transgenerational effects.

The recommendation of the CHM is not considered to be a ban on new prescriptions in patients up to the age of 55 years. Rather CHM concluded that there should be greater clinical oversight of such prescriptions. Therefore, it was recommended that two specialists must independently consider and document there are no other effective or tolerated treatments apart from valproate for that patient.

CHM recommended the development of an implementation group to advice on the introduction of the proposed new safety measures. No changes to valproate prescribing are currently required until the CHM considers of the advice of the implementation group. In line with standard procedure, a public assessment report (PAR) will be published by the MHRA summarising the data considered which underpin the recommendations for the updated regulatory position for valproate. Given the plans to publish the PAR and the consideration of the implementation of the recommendations is ongoing, it is not possible to release the data under section 22 and section 53 of the FOI Act 2000 until the implementation plan has been finalised and supporting communications are provided to healthcare professionals across the UK.

We will of course send you a link to the published public assessment report once available.

The relevant sections of the FOI Act are outlined below.

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
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

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Regulatory Agency

Yours sincerely,

Safety and Surveillance