Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00560**

18 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 19 May. You wrote:

> *We wish to request the most recently approved version of the Risk Management Plan (RMP) prepared by the MAH AGB Pharma, for melatonin products which includes "off-label use in children under the age of 6, long term safety in children and adolescents, effects on sexual maturation and development in children and adolescents" as important potential risks and, "fertility, pregnancy and lactation" under missing information.*
>
> *Thank you in advance for your support on this matter. I look forward to hearing further from you.*

MHRA Response

We can confirm that the MHRA holds a copy of the requested Risk Management Plan (RMP) for Adaflex. Please find the document attached.

Please be aware that some information has been redacted from the document as it is exempt from disclosure under the Freedom of Information Act 2000 (FOIA).

Section 40(2) – Personal Information
Certain information has been withheld under section 40(2) of the FOIA. This exemption applies to personal data relating to identifiable individuals. Disclosure of this information would contravene the data protection principles set out in the UK General Data Protection Regulation and the Data Protection Act 2018. The information has therefore been withheld.

Section 41 – Information Provided in Confidence
Certain information has been withheld under section 41 of the FOIA. This exemption applies to information that was obtained from another person and is subject to an obligation of confidence. Disclosure of this information would constitute an actionable breach of confidence. The information has therefore been withheld.

Section 43(2) – Commercial Interests
Certain information has been withheld under section 43(2) of the FOIA.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency.

It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category.

In this instance we feel that the release of this information could prejudice the commercial interests of the company by disclosing commercially sensitive sales figures, which could provide competitors with insight into the commercial performance of the product.

As required by the FoI Act the use of this exemption requires the public interest for and against disclosure to be assessed.

Public Interest Test
In considering the public interest test, we recognise that there is a potential benefit in disclosing information from the RMP as it would promote transparency. However, this is outweighed by the need to maintain the exemption in this instance. The redactions made are appropriate and proportionate, as they safeguard commercially sensitive information such as sales figures. It is important to note that every RMP has a summary which is available in the public domain.

Having considered the factors for and against disclosure, we have concluded that the public interest in maintaining the exemption outweighs the public interest in disclosure. The commercially sensitive information has therefore been withheld under section 43(2).

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,
MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make

a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/