Medicines & Healthcare products
Regulatory Agency

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

3 May 2024

MHRA reference: FOI2024/00087

Dear [redacted],

Thank you for your information request of 2 May. Your requests were:

1) *Can you tell me all actions MHRA took following reports of eye damage incurred after of use of Epimax products both before, during and after Aspire Pharma's issuing of field safety corrective notice Ref NC/D707. I am particularly interested in any review MHRA may have undertaken regarding the field safety corrective action notice and whether it was approved as suitable and appropriate action. Did anybody at MHRA have any concerns that the action proposed by Aspire Pharma might not be adequate, and did anybody check that the changes had been carried out as described?*

2) *Can you tell me also how many yellow card notices you have ever received about Epimax products.*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

With regard to your first request, we confirm that we hold the information you have asked for. In response to your request, we are providing information relating to your first question on the actions of the MHRA around Aspire Pharma issuing a Field Safety Notice (FSN) in January 2023 on various Epimax products.

The MHRA was informed of a potential signal involving certain Epimax emollients and initiated an investigation into the signal, which included discussions with the manufacturer, Aspire Pharma, as well as relevant NHS stakeholders. Aspire Pharma determined that that a Field Safety Corrective Action was required and prepared a draft Field Safety Notice (FSN) to inform their customers of this, which they sent to

the MHRA for comment. The MHRA encourages manufacturers to send draft FSNs for comment, however, this is not a requirement, and as the FSN is the manufacturer's document, the MHRA does not approve FSNs. The MHRA provided comments on the draft FSN to Aspire Pharma and the final FSN was issued by Aspire Pharma on 20 January 2023. Following publication of the FSN, the MHRA monitored the effectiveness of the FSN, and the MHRA investigation was closed in October 2023.

I would like to draw your attention to the guidance on our website to manufacturers on Field Safety Corrections Actions and provide an outline of MHRA process after a field safety notice has been published - https://www.gov.uk/guidance/effective-field-safety-notices-fsns-guidance-for-manufacturers-of-medical-devices.

With regard to your second request, we consider that the number of Yellow Card reports the MHRA has received regarding Epimax products is exempt under section 43(2) of the FOIA.

Under section 17(1) of the FOIA, when we refuse any part of the requested information, we must specify the relevant exemption and explain why the exemption applies.

For section 43(2) this is a prejudice-based exemption, which means that information is exempt if its disclosure under FOIA would, or would be likely to, prejudice the commercial interests of any legal person (including the public authority holding it). [1] A 'commercial interest' relates to a legal person's ability to participate competitively in a commercial activity.

The MHRA holds commercial information to undertake regulatory activity and we can hold commercially sensitive information obtained in the course of our investigations or related to our functions.

For information to be exempt from disclosure under section 43(2), the MHRA must be able to show that the disclosure of the information would, or would be likely to, prejudice or harm commercial interests of an individual, a company, the public authority or any other legal entity; we need to identify what the harm is and why it may occur as a result of disclosure with the risk of prejudice occurring being "real and significant, and there must a 'causal link' between the disclosure of the information in question and the prejudice we believe will occur.

Aspire Pharma have identified how disclosure would be likely to cause prejudice to their commercial interests, as it would be used by their direct competitors to cause reputational damage and reduce sales.

S43(2) of the FOIA is a qualified exemptions and so also requires consideration of the public interest in disclosure and in maintaining the exemption. On balance we do not find any significant public interest value so as to outweigh the prejudice that

would be caused to the company's commercial interests in a highly competitive industry. Disclosure of the information would cause harm to the company concerned if released as the information could be used by their direct competitors to cause reputational damage and reduce sales. We therefore consider that the public interest in maintaining the exemption outweighs the public interest in disclosure of the withheld information, and that section 43(2) therefore applies.

If it would be helpful, we could provide information on the number of Yellow Cards for all emollients. Please inform us if you would like this information.

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Safety and Surveillance Group

Medicines and Healthcare products Regulatory Agency

[1] https://ico.org.uk/for-organisations/foi/freedom-of-information-and-environmental-information-regulations/section-43-commercial-interests/

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/ or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Re-use of our information

Medicines & Healthcare products
Regulatory Agency