Medicines & Healthcare products
Regulatory Agency

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

[redacted]

01/08/2024

MHRA reference **FOI2024/00297**

Dear [redacted],

Thank you for your information request, which we received on 16th July 2024. You asked for:

> ***"I request you to provide the most recently submitted and approved Risk Management Plan (RMP) for following products,***
>
> ***1. Lorazepam 1mg and 2.5mg Tablets***
>
> ***PL 48278/0016-0017***
>
> ***MAH - Zista Pharma Limited***
>
> ***And***
>
> ***1. Lorazepam 0.5mg, 1mg and 2.5mg Tablets***
>
> ***PL 30322/0054-0056***
>
> ***MAH - Alissa Healthcare Research Ltd"***

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

We can confirm that the MHRA holds a copy of the requested RMP for Lorazepam 1mg and 2.5mg Tablets (PL 48278/0016-0017) and Lorazepam 0.5mg, 1mg and

Medicines & Healthcare products
Regulatory Agency

2.5mg Tablets (PL 30322/0054-0056). Please find these documents attached to the email.

Information that has been redacted is exempt under Section 40 (Personal Information) or Section 43 (Commercial Interests) of the Freedom of Information (FOI) Act and is therefore withheld.

Section 40 provides that personal information may be exempt from release where to do so would contravene data protection principles. Section 43 provides that information will be exempt from release where to do so would or would be likely to prejudice commercial interests. Furthermore, we do not believe that there is an overriding public interest in disclosing the redacted information in this instance.

We hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

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

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/

Medicines & Healthcare products
Regulatory Agency

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/

If you re-use our information, you should include the following attribution, including a link to the OGL v3.0:

> Medicines and Healthcare products Regulatory Agency, [name and date of publication], licensed under the Open Government Licence.

For further information on the reproduction or re-use of MHRA information, please visit https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information.