FOI 23/165 Minoxidil RMP and Risk Minimisation

REQUEST

3 March 2023

Please can you provide us with copies of the RMP and any risk minimisation measures for Minoxidil 2.5mg, 5mg and10mg Tablets, including any Annex 4 - targeted follow-up questionnaires in the event of receipt of cases of use in pregnancy/lactation, or off-label use in the treatment of alopecia.

MHRA RESPONSE

14 March 2023

Thank you for your email, dated 3rd March 2023, in which you requested:

“a copy of the Risk Management Plan for Minoxidil 2.5mg, 5mg and 10mg Tablets, and the Risk Minimisation”

We can confirm that the MHRA holds a copy of the requested RMP and the Risk Minimisation.

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.

Please remember to quote the reference number above in any future communications.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

only entitles you to access to MHRA information.

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