

FOI 23/741

Dear

Thank you for your FOI request dated 5th October 2023.

"I request you to kindly provide the most recently submitted (available) risk management plans (RMP) for Norethisterone 5 mg Tablets from the company given below:

Norethisterone 5mg Tablets

Wockhardt UK Ltd Ash Road North Wrexham LL13 9UF U.K.

PL 29831/0152"

We can confirm that we do not hold the information that you have requested. As the original marketing authorisation applications for PL 29831/0152 and PL 00057/1054 were made prior to the 2012 amendment in pharmacovigilance legislation, which requires an RMP for all new applications, the MHRA does not hold an RMP for these products.

If you have a query about the information provided, please reply to this email.

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

Yours sincerely

FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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

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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