FOI 24/153 - FoI Request: RMP- Hydrocortisone

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Thu 07/03/2024 14:07

To ███ >

Our ref: FOI 24/153

Dear ████████████████

Many thanks for your Freedom of Information (FOI) request for the following information:

> "I would like to request a copy of the latest PAR for Hydrocortisone 5mg Tablets, Glenmark Pharmaceuticals Europe Ltd (PL 25258/0321) for RMP preparation/ update to the existing RMP for Hydrocortisone Tablets Morningside Healthcare Ltd."

Please note that this product was cancelled on 12 January 2024. According to our records, the latest version of the Risk Management Plan (RMP) that was submitted for this product was for the initial marketing authorisation of this product.

The assessment of that RMP is included in the PAR that is linked below: https://mhraproducts4853.blob.core.windows.net/docs/e6ce9114ad9b993d896073ffd65c5c54dd6b9dbb

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

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

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

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: ███
Sent: Thursday, February 15, 2024 2:58 PM