Medicines & Healthcare products
Regulatory Agency

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

[redacted]

30 May 2024

MHRA reference FOI2024/00086

Dear [redacted]

Thank you for your information request, which we received on 2 May. You asked for:

> *"Please share the latest available Risk management Plans for the following under the Freedom of Information Act*
>
> *KLEAN-PREP 69G SACHET POWDER FOR ORAL SOLUTION<https://mhraproducts4853.blob.core.windows.net/docs/960206536c678690f316ffa32116875e88a83b5a>*
> *PL 00322-0068<https://mhraproducts4853.blob.core.windows.net/docs/960206536c678690f316ffa32116875e88a83b5a>*
>
> *MOVIPREP POWDER FOR ORAL SOLUTION<https://mhraproducts4853.blob.core.windows.net/docs/33096b08f1e0a339d3ccec00ea435651556ecbae>*
> *PL 20011-0039<https://mhraproducts4853.blob.core.windows.net/docs/33096b08f1e0a339d3ccec00ea435651556ecbae>*
>
> *PLENVU POWDER FOR ORAL SOLUTION<https://mhraproducts4853.blob.core.windows.net/docs/80865401349fcaa3acd415c02b0358a2c30a36c5>*

PL 20011-0040<https://mhraproducts4853.blob.core.windows.net/docs/80865401349fcaa3acd415c02b0358a2c30a36c5>

LONITEN 5 MG TABLETS<https://mhraproducts4853.blob.core.windows.net/docs/0120513f034b2bb57b08a63aa0fe2e878cd446e5>
PL 00057-1007<https://mhraproducts4853.blob.core.windows.net/docs/0120513f034b2bb57b08a63aa0fe2e878cd446e5>"

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 Moviprep Powder for Oral Solution (PL 20011-0039) and PLENVU powder for oral solution, (PL 20011-0040). Please find these documents attached to the email.

We also confirm there is no RMP for Klean-Prep 69g Sachet, Powder for Oral Solution (PL 00322/0068) and Loniten 5 mg Tablets (PL 00057/1007) as the Marketing Authorisation applications were made prior the 2012 amendment in pharmacovigilance legislation, which requires an RMP for all new applications therefore the MHRA does not hold this information.

Information that has been redacted from the RMPs is exempt under Section 40 (Personal Information) 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. 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 & Healthcare products Regulatory Agency

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/

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

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