FOI 23/633

Thank you for your email, dated 23rd August 2023, in which you requested:

"a copy of the Risk Management Plan for PL 23860/0015, PL 00057/0106R and PL 04425/0370"

We can confirm that we do not hold the RMPs for PL 00057/0106R and PL 04425/0370 as the original marketing authorisation applications for these products were made prior to the 2012 amendment in pharmacovigilance legislation, which requires an RMP for all new applications.

We can confirm that the MHRA does hold the requested RMP for PL 23860/0015, a copy of which is attached. 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