FOI 22/1137

5th January 2023

Dear

Thank you for your email, dated 23rd November 2022, in which you requested:

• Whether the EU Safety Risk Management Plan (RMP) version 5.1 dated 18Mar2016 for Zofran, Novartis that is registered in the United Kingdom is the most current or a new version has been issued?

• If a new version has been issued, could you please share the summary of the RMP or the list of safety concerns?

We can confirm that the MHRA holds a copy of the latest version of the RMP (v6.0) and it has been 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