Medicines & Healthcare products Regulatory Agency

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London
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United Kingdom
gov.uk/mhra

[redacted]

Email: [redacted]

08 May 2024

Dear [redacted]

FOI 24/252: Mounjaro KwikPen - PLGB 14895/0340-0345

Thank you for your communication, dated 11 March 2024, in which you requested Module 2.7 submitted for Mounjaro 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg and 15 mg KwikPen solution for injection in pre-filled pen (PLGB 14895/0340-0345).

In response to your request, please find attached Modules 2.7.1, 2.7.1.4, 2.7.2, 2.7.3, 2.7.4, 2.7.5 and 2.7.6 submitted to support the initial applications for Mounjaro 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg and 15 mg KwikPen solution for injection in pre-filled pen (PLGB 14895/0340-0345). Please note that the documentation for Module 2.7.1 and Module 2.7.1.4 has been redacted under Section 40 (Personal information), Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the Freedom of Information (FOI) Act.

Disclosure of information subject to Section 40 (Personal information) would be an infringement of personal data. Section 40 (Personal information) is an absolute exemption, and no consideration of the public interest is required.

Section 41 (Information given in confidence) is an absolute exemption, and no consideration of the public interest is necessary, except to state that the release of this information withheld under this section of the FOI Act would be considered an actionable breach by the MHRA.

We have redacted some parts of Module 2.7.1 and Module 2.7.1.4 under Section 43 (Commercial interests) of the FOI Act because the release of all, or part of, the information

would be likely to cause harm to the third party's commercial interests. The exemption is to safeguard the commercially sensitive information/commercial enterprise. In this case, release of information would enable competitors to overcome several regulatory hurdles in the research and development of their own products. This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. We have considered the balance of the public interest when applying this exemption. In this case, we have not identified any issues which would benefit the public, as a whole, by being brought to their attention.

We trust that you will find this information of use. If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: 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.

Yours sincerely,

The FOI Team,
Healthcare Quality and Access.