FOI 23/673

Dear

Thank you for your patience. Following the completion of a public interest test (PIT) we have now finalised our response to your FOI request.

> *Please could you disclose the Public Assessment Report and the Clinical Overview (Module 2.5) for Omeprazole (2mg/ml, 4mg/ml) powder for oral suspension marketed by Rosemont Pharmaceuticals Limited.*
>
> *the correct MAH for this product is Xeolas Pharmaceuticals Limited. The MA number is PL34111/0005.*

Please find attached the clinical overview for Omeprazole (1mg/ml) powder for oral suspension (PL 34111/0005).

Redactions have been made under Sections 40(2), 41, Section 43(1), and 43(2) of the FOIA.

Sections 40(2) (personal information, of which the applicant is not the data subject)
I can confirm that the only material we have redacted is that which concerns personal data: this information is withheld as it falls under the exemption in sections 40(2) and 40(3)(a)(i) of the FOIA, which relates to the personal data of which the applicant is not the data subject. Section 40(2) of the FOIA provides that personal data relating to other persons is exempt information if disclosure would breach the Data Protection Act 1998 (DPA). We consider that disclosure of this information is likely to breach the first data protection principle in Schedule 1 to the DPA, which relates to the fair and lawful processing of personal data. Therefore, we have concluded that this information is exempt from disclosure under section 40(2) read in conjunction with section 40(3)(a)(i) of the FOIA.

Section 41(1) (information provided in confidence) is an absolute exemption and no consideration of the public interest is required. The withheld information was provided to the MHRA in confidence by a third-party for the purposes of assessment. This information has the necessary quality of confidence as it is more than trivial and not otherwise accessible; the preservation of confidences is recognised by the courts to be an important matter and one in which there is a strong public interest. In this case, the information was provided to the MHRA with explicit conditions on its use by the MHRA (including further disclosure) and an obligation of confidence therefore exists. For these reasons, disclosure would be likely to have a detrimental impact on the party who provided the information. In such circumstances, our view is that disclosure would be an actionable breach of that confidence, and this engages the section 41(1) exemption.

43(1 &2)
Release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests.

We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). 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. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity) .

We trust that you will find the attached information of use. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

Or

by writing to:
Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Yours sincerely
MHRA Customer Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Yours sincerely,

HQA FOI Team