Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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E14 4PU

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MHRA Website

[redacted]

Our Ref: **FOI2024/00734**

15 January 2025

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 21 November. You wrote:

> *PL 43461/0076, Carbimazole 10mg tablets, Flamingo*
> *PL 43461/0104, Carbimazole 15mg tablets, Flamingo*
>
> *Under the FOI I would like to request module 2 documents for the above 2 MAs. This includes 2.3.P.1-quality overall summary, 2.4.P-non-clinical overview, 2.5.P- clinical overview, 2.7.P- clinical summary*

MHRA Response

The Agency has completed its search for the information you have requested, and we are able to confirm that we do hold the information you have requested.

Please find the non-clinical overview, clinical overview and clinical summary attached.

Please note that some redactions have been applied to these documents. We are withholding this information under the following exemptions, Section 21(1), Section 40(2) (Personal information), Section 41(1) (Information given in confidence), and Section 43(1) and 43(2) (Commercial interests) of the FOI Act.

The quality overall summary you requested is being withheld in its entirety as it falls under the exemption of Section 43(2) (Commercial interests) of the FOI Act.

Some of the information with the above documents, such as the qualitative composition of the products is releasable. However, as this information is available in the published Summary of Product Characteristics (SmPC), the information is exempt under Section 21(1) of the FOI Act. A link to the MHRA Product Portal, from which the SmPC can be obtained is provided below: MHRA Products | Home

Section 21:
The information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible, as it is already in the public domain.Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this

case the condition contained in Section 40(3A) (a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FOI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject. Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

MHRA maintains the following policy on disclosure of personal information:
"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

Section 41:
(1) Information is exempt information if — (a) it was obtained by the public authority from any other person (including another public authority), and (b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.

Section 43 (Commercial interests):
(1) Information is exempt information if it constitutes a trade secret.
(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The ‘public interest’ is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The ‘right to know’ must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is ‘applicant blind’. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of releasing the information
To release information on the quality information and quantitative composition for these products would be of benefit in general by providing information about the products and showing transparency in MHRA’s day-to-day work to the public.

Considerations in favour withholding the information
Detailed information on the quality information and quantitative composition is commercially sensitive information that has been provided to MHRA in confidence. The marketing authorisation holder has spent a lot of time and money in developing the product and this information can be used by rival companies to overcome regulatory hurdles at the expense of the marketing authorisation holder.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

If you have any queries about this letter, please contact us quoting the reference number above.

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Yours sincerely,

MHRA Central Freedom of Information Team
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Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information