NOW SENT FOI 24/257 Clonidine 25 mcg Tablets (PL 56854/0016)

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sun 24/03/2024 12:48
To [redacted]

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: 24 March 2024 12:47
To: [redacted]
Subject: FOI 24/257 Clonidine 25 mcg Tablets (PL 56854/0016)

Dear [redacted]

Regarding your request under the Freedom of Information Act (FOIA) for "the Quantitative and Qualitative formula for Dixarit 25 mcg Tablets (PL 00015/5014R; MAH: Boehringer Ingelheim Limited)", please see the qualitative composition taken from the final approved version of the Summary of Product Characteristics (SmPC) for this product below:

Tablet core:
Calcium hydrogen phosphate, anhydrous
Lactose monohydrate
Maize starch
Colloidal anhydrous silica
Povidone
Maize starch soluble
Indigo carmine (E132)
Magnesium stearate

Tablet coating:
Povidone
Sucrose
Talc
Acacia
Titanium dioxide (E171)
Indigo carmine (E132)
Macrogol
Carnauba wax
White beeswax

The quantitative composition for this product is exempt from release under Section 41(1) and Section 43(2) of the FOIA.

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.

43.
(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).

(3)The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the provision 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 refusing outweighs the public interest in providing any information we hold. 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 releasing further information on this issue. 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 providing information
To provide the quantitative composition for this product would be of interest to other companies in aiding the development of their products, so getting these products to the public quicker. It would also be of benefit in general to show transparency in the data that MHRA receives.

Considerations in favour of refusing to provide information
To provide the quantitative composition of a medicine would be of great interest to rival companies who are looking to market their own products. This knowledge can be used by competitors to overcome regulatory hurdles in getting their products authorised and on the market, at the expense of the owner of this product. This can create a chilling effect, with companies reluctant or unwilling to submit applications for their products to the UK, if MHRA is willing to give away trade secrets on request. This would result in fewer medicines being available for patients. It should be noted that the quantitative composition is considered to be a trade secret and is exempted from release in agreement with the Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) guidance on transparency, linked below:
https://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/07-Transparency/2012_03_HMA_EMA_Guidance_20120309_ComPersInfo.pdf

If you have a query about the information provided, please reply to this email.

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 you receive this response and addressed to: info@mhra.gov.uk

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 at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

MHRA Customer Experience Centre
Communications and Engagement Team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Wednesday, March 13, 2024 1:50 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/257 Clonidine 25 mcg Tablets (PL 56854/0016)

Dear MHRA Team,

Please provide Quantitative and Qualitative formula for Dixarit 25 mcg Tablets (PL 00015/5014R; MAH: Boehringer Ingelheim Limited)

Under Freedom of Information Act, we request the agency to kindly provide above information.

We have received RFI from UK-MHRA that to present data to show that excipients that may impact absorption are qualitatively the same and quantitatively similar (within ±10% of reference product).

Since, Reference product is discontinued from the market, we request the agency to provide information.

Regards,
[redacted]