Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2024/00740**

17 December 2024

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 22 November 2024. You wrote:

> *I noticed that there are a lot of Bristol products, but I want to make sure that they are manufactured in the United Kingdom. Can your organization help me to confirm the source of this company?*

MHRA Response
We can confirm that the Agency holds the information you are seeking.

However, the information you have requested is commercially sensitive and is, therefore, exempt from release under Section 41(1), and Section 43(1)/Section 43(2) of the FOI Act.

We will explain these exemptions below.

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:
(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).

Regarding the use of Section 41, the information you have requested relates to the finished product manufacturers for marketing authorisations currently held by Bristol Laboratories Limited. This information was obtained by the Agency from this marketing authorisation holder and the Agency believes that if this information were released it would be an actionable breach of confidence. Therefore, we are not going to be releasing the requested information.

Regarding the use of Section 43, this exempts information which if disclosed would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties, but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or

services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category. In order to apply Section 43 properly, a consideration of the public interest (public interest test) is required.

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 this information would benefit in general by showing transparency in MHRA's day-to-day work to the public for the public to see all sites related to the manufacture of an authorised medicine.

Considerations in favour withholding the information
Information on the manufacturing sites used by marketing authorisation holders for their products is commercially sensitive information that has been provided to MHRA in confidence. To publish this information would be to provide competitor companies with information on where this product can be sourced, helping these companies in sourcing their own product manufacturers to the commercial detriment of the marketing authorisation holder concerned (in this case Bristol Laboratories Limited).

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

This decision is in compliance with the Heads of Medicines Agencies/European Medicines Agency (HMA/EMA) guidance on transparency, where on pages 14 and 34 it states that the finished product manufacturers are commercially confidential information (CCI) and, therefore, are exempt from release.
HMA/EMA GUIDANCE DOCUMENT ON THE IDENTIFICATION OF COMMERCIALLY CONFIDENTIAL INFORMATION (europa.eu)

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

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

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
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/