Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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London
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MHRA Website

[redacted]

Our Ref: **FOI2026/00949**

17 October 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 25 August. You wrote:

> *Thank you for your response regarding FOI requests FOI2026/00814 and FOI2026/00815.*
>
> *In accordance with your request to reduce the scope of the FOI request, I confirm that I would like to proceed with FOI2026/00815 only, relating to the following Marketing Authorisation:*
>
> *Marketing Authorisation Holder: Dawa Ltd*
> *Product: Cyanocobalamin 50 microgram Film-coated Tablets*
> *PL Number: 30684/0243*
> *FOI Reference: FOI2026/00815*
>
> *The information requested remains limited to Module 2.4, Module 2.5 and Module 2.7 submitted in support of the above Marketing Authorisation.*
>
> *Please proceed with the processing of FOI2026/00815 on this reduced scope.*
> *Thank you for your assistance.*

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

In response to your request, please find attached the Clinical Overview and Non-Clinical Overview for Cyanocobalamin 50 microgram film-coated tablets from Dawa Limited (PL 30684/0243).

Following a search of our electronic records, we have established that Module 2.7 is not held by this Agency.

Please note that the documentation provided has been redacted under Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the Freedom of Information Act.

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 the attached documentation under Section 43 (Commercial interests) of the FOI Act because the release of all, or part of, the information would, or 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 the 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.

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/