Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Refs:
FOI2026/00332,
FOI2026/00344
FOI2026/00346

24 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) requests received on 25 and 26 March.

For FOI2026/00332 you wrote:

I am writing to request information under the Freedom of Information Act 2000. Injectable hydroxocobalamin and cyanocobalamin products formulated for veterinary use are available in the United Kingdom without a prescription, including via online veterinary pharmacies and agricultural suppliers. Injectable hydroxocobalamin formulated for human use is classified as a prescription-only medicine (POM).

Please provide:
Any internal assessments, advice, or correspondence held by the MHRA that addresses the differential regulatory treatment of injectable B12 products for human versus veterinary use, including any consideration of whether this differential creates a patient safety risk through off-label sourcing of veterinary products by human patients.
Any evidence that the MHRA is aware of patients sourcing veterinary injectable B12 products for self-administration, and any action taken or considered in response.

Any communications between the MHRA and the Veterinary Medicines Directorate (VMD) regarding the classification of injectable B12 products and the implications of the difference in human and veterinary regulatory status. I am writing to request information under the Freedom of Information Act 2000.

For FOI2026/00344 you wrote:

Cyanocobalamin and hydroxocobalamin injection ampoules are available for purchase without a prescription in several EU member states, including France and Germany. In the United Kingdom, these products are classified as prescription-only medicines (POM).

Please provide:
The date on which hydroxocobalamin and/or cyanocobalamin injection ampoules were classified as prescription-only medicines in the UK, and the regulatory instrument or process by which this classification was established.

Any internal assessments, advice, or correspondence held by the MHRA that informed or

supported the decision to classify these products as prescription-only rather than pharmacy (P) or general sale medicines.

Any communications between the MHRA and the Department of Health and Social Care, NHS England, or NICE regarding the prescription-only classification of injectable B12 products, from January 2000 to the present date.

For FOI2026/00346 you wrote:

I am writing to request information under the Freedom of Information Act 2000.
Please provide:

Details of any applications received by the MHRA to reclassify hydroxocobalamin or cyanocobalamin injection ampoules from prescription-only medicine (POM) to pharmacy (P) status, including the date received, the applicant, and the outcome.
If no such applications have been received, please confirm this in writing.
Any horizon-scanning reviews, internal papers, or correspondence in which the MHRA has considered whether the current POM classification of injectable B12 remains appropriate, from January 2010 to the present date.

MHRA Response

Please find our response to each of your requests below.

FOI2026/00332

We have established that the information you requested is not held by this Agency.

The MHRA regulates human medicines, including vaccines, supplied in the UK. We decide whether medicines should be granted licences (also known as Marketing Authorisations) and whether the licences can be varied as information about the medicines develop. These decisions are based on safety, quality and effectiveness data submitted to us.

The off-label use of veterinary medicines does not fall within our remit. Adverse reactions in humans from the use of veterinary medicines can be reported to the Veterinary Medicines Directorate (VMD). The VMD may be able to assist you further with this request and can be contacted at postmaster@vmd.gov.uk.

FOI2026/00344

Currently and previously granted Marketing Authorisations (Product Licences; PLs) for cyanocobalamin and hydroxocobalamin injection/infusion products have always had a legal classification of prescription only medicine (POM).

Product Licences of Right (PLRs) were given automatically to products that were already on the UK market when the Medicines Act 1968 came into force, allowing these products to continue being marketed. PLRs later underwent formal regulatory review, becoming reviewed licences.

Some cyanocobalamin and hydroxocobalamin injection/infusion products with pharmacy status were given PLRs. However, none of these PLRs were granted as reviewed licences and were cancelled.

Please note that the criteria for classification are set out in Regulation 62 of the Human Medicines Regulations 2012. Regulation 62(3) is clear that if the medicine is usually prescribed for parenteral administration – that is by injection – then the medicinal product must by law be classified as a prescription only medicine.

The following guidance provides information on the reclassification of medicines in the UK. Please refer to page 18 for the POM criteria. Please note that cyanocobalamin and hydroxocobalamin injection/infusion products meet the fourth POM criterion:

Parenteral administration entails piercing the skin or mucous membranes. Products intended for parenteral administration are unsuitable for reclassification due to the heightened risks and complexities associated with this route of administration, making medical supervision necessary for their availability.

https://assets.publishing.service.gov.uk/media/67c6eea572e83aab48866dd0/MHRA_guidance_on_the_reclassification_of_medicines_in_the_UK.pdf

FOI2026/00346
We can confirm that no applications to reclassify hydroxocobalamin or cyanocobalamin injection ampoules from prescription-only medicine (POM) to pharmacy (P) status have been granted by MHRA.

Regarding pending applications and any related assessments/reviews/correspondence, unfortunately, we cannot provide information on whether there may or may not be an application in progress for any particular product. When we need to refuse a written request for information in this way, we need to do this under the provisions of the Freedom of Information Act 2000 (FOIA) so that we include the relevant exemptions and the reasons why we are applying them. This means that for your enquiry we need to refuse to confirm or deny whether we hold this information under Section 41(2) (S41 – information provided in confidence) and Section 43(3) (S43 – prejudice to commercial interests) of the FOIA.

We will explain these exemptions below.

Section 41 –
(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.

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).
(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 neither confirm nor deny 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 neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. 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 saying whether information is held or not. 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 confirming whether or not we hold the information
To confirm or deny whether or not an application has been received by MHRA would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients under a different legal classification. It would also be of benefit in general to show transparency in MHRA's day-to-day work for the public to see what applications are currently being considered by MHRA.

Considerations in favour of neither confirming nor denying whether we hold the information
To confirm or deny whether we are currently considering an application for a particular medicine would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is being considered by MHRA can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to confirm or deny that we may hold any information on applications that are not yet authorised in the UK can create a chilling effect, with companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

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
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/