



foi.request@mhra.gov.uk

[MHRA Website](#)

Our Ref: **FOI2026/00452**

22 May 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 24 April. You wrote:

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

Background

In response to my earlier FOI request (FOI2026/00344), the MHRA confirmed that injectable hydroxocobalamin and cyanocobalamin are classified as prescription-only medicines (POM) under Regulation 62(3) of the Human Medicines Regulations 2012, on the basis that 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.

However, a number of injectable medicines are routinely self-administered by patients at home without direct medical supervision at the point of administration, following initial training. These include but are not limited to:

Insulin

Subcutaneous methotrexate

Injectable fertility treatments (for example gonadotrophins) Biologic medicines for conditions including rheumatoid arthritis and Crohn's disease (for example adalimumab, etanercept) Growth hormone preparations requiring reconstitution from vials

Several of these products require considerably greater technical skill to prepare and administer than a simple ampoule injection, yet home self-administration is standard clinical practice for them.

This appears to create an inconsistency in the application of Regulation 62(3). The regulation as cited treats parenteral administration as a uniform category requiring medical supervision. Actual regulatory and clinical practice does not treat it as uniform.

Please provide:

Any internal guidance, policy documents, or assessments held by the MHRA that explain how Regulation 62(3) is applied differentially across injectable medicines, including the criteria used to determine when home self-administration is considered acceptable for a POM injectable product.

Any internal assessments, advice, or correspondence held by the MHRA that specifically addresses the safety profile of injectable hydroxocobalamin in the context of home self-administration, including any assessment of its therapeutic index, known toxicity ceiling, or adverse event profile compared with other injectable medicines routinely self-administered at home.

Any communications held by the MHRA between its licensing, classification, or policy teams regarding whether the current POM classification of injectable hydroxocobalamin remains proportionate given its established safety profile, from January 2010 to the present date.

Any risk assessments or benefit-harm analyses conducted by the MHRA comparing the risks of maintaining the current POM classification of injectable B12 (including the risk of patients sourcing unregulated alternatives) against the risks of reclassification to pharmacy or supervised pharmacy status.

The criteria the MHRA applies when determining that a parenteral medicine may be suitable for patient self-administration at home, and whether injectable hydroxocobalamin has ever been assessed against those criteria.

MHRA Response

Please find our response to each part of your request below.

Any internal guidance, policy documents, or assessments held by the MHRA that explain how Regulation 62(3) is applied differentially across injectable medicines, including the criteria used to determine when home self-administration is considered acceptable for a POM injectable product.

MHRA Response:

Regulation 62(3)(d) of the Human Medicines Regulations 2012 specifically requires any medicine “normally prescribed by a doctor or dentist for parenteral administration” to be available only on prescription. Our published reclassification guidance confirms that products for injection are not appropriate for prescription-only medicine (POM) to pharmacy (P) reclassification. This reflects the fourth POM criterion: injections are unsuitable for supply without prescription due to the heightened risks of invasive administration, which necessitate medical supervision for their availability.

You have asked how Regulation 62(3) is differentially applied across different injectable medicines. The criteria are applied uniformly to all human medicinal products. Under Regulation 62(3), a medicine is designated POM if any one of the statutory conditions is met.

Please refer to the links below:

[Medicines: reclassify your product - GOV.UK](#)

<https://www.legislation.gov.uk/uksi/2012/1916/regulation/62/made>

https://assets.publishing.service.gov.uk/media/65f981489316f5001d64c29b/Final_reclassification_guidance_180324.pdf

You have highlighted examples of injectable medicines (insulin for diabetes, subcutaneous methotrexate, fertility treatments like gonadotrophins, biologic therapies such as adalimumab/etanercept, and growth hormones) that patients routinely self-administer at home after clinical training. We confirm that all these products are classified as POM.

Patients may inject these medicines themselves only after a qualified prescriber (e.g. specialist or GP) has:

- (1) diagnosed the condition,
- (2) assessed that the medicine is appropriate,
- (3) initiated therapy with monitoring plans, and
- (4) provided training or arranged for it.

The prescriber remains responsible for ongoing supervision and dose adjustments. For example, insulin therapy is managed by doctors who determine dosing and monitor glycaemic control; similarly, methotrexate for rheumatoid arthritis or biological injections require specialist oversight throughout treatment, even if injections are given by the patient at home. In each case, continuing clinical management and regular review by healthcare professionals is required.

Vitamin B12 injections fall under the same rules that cover those other drugs: all are POM because safe use requires a prescriber's initial diagnosis and continued oversight. There is, therefore, no special or differential treatment for Vitamin B12 injection products.

There is no single set of criteria that determines whether a medicine is suitable for patient self-administration. For some medicines, the marketing authorisation is granted on the basis that the product will be self-administered, and this is clearly described in the product information.

Any internal assessments, advice, or correspondence held by the MHRA that specifically addresses the safety profile of injectable hydroxocobalamin in the context of home self-administration, including any assessment of its therapeutic index, known toxicity ceiling, or adverse event profile compared with other injectable medicines routinely self-administered at home.

MHRA Response:

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

You may be interested in the attached guidance that was issued by the National Institute of Clinical Excellence (NICE) regarding the diagnosis and management of Vitamin B12 deficiency. The guidance includes a section on self-administration of Vitamin B12 replacement injections and a recommendation for further research in this area to inform future guidance.

[Recommendations for research | Vitamin B12 deficiency in over 16s: diagnosis and management | Guidance | NICE](#)

Any communications held by the MHRA between its licensing, classification, or policy teams regarding whether the current POM classification of injectable hydroxocobalamin remains proportionate given its established safety profile, from January 2010 to the present date.

MHRA Response:

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

As described in our previous response to FOI2026/00344, and explained further above, the criteria for classification are set out in Regulation 62 of the Human Medicines Regulations 2012. The reclassification of vitamin B12 injections to non-prescription medicines to enable these to be purchased over-the counter is not supported by current legislation.

Any risk assessments or benefit-harm analyses conducted by the MHRA comparing the risks of maintaining the current POM classification of injectable B12 (including the risk of patients sourcing unregulated alternatives) against the risks of reclassification to pharmacy or supervised pharmacy status.

MHRA Response:

In terms of general risk assessments or benefit/harm analysis regarding the POM status of Vitamin B12 as a whole, we have established that the information you requested is not held by this Agency.

The reclassification of vitamin B12 injections to non-prescription medicines to enable these to be purchased over-the counter is not supported by current legislation.

Regarding any specific applications to reclassify Vitamin B12 from POM to P status, we can confirm that no applications to reclassify injectable Vitamin B12 from POM to P status have been granted by MHRA.

Regarding pending applications and any related assessments, unfortunately, we cannot provide information on whether there may or may not be an application in progress for any particular product. Please refer to our response to FOI2026/00346 and IR2026/00451.

The criteria the MHRA applies when determining that a parenteral medicine may be suitable for patient self-administration at home, and whether injectable hydroxocobalamin has ever been assessed against those criteria.

MHRA Response:

There is no single set of criteria to determine whether a medicine is suitable for patient self-administration. This will be assessed for an individual application where the application is for a product that is intended to be self-administered. Licences are granted based on safety, quality and effectiveness data submitted to us.

The hydroxocobalamin products licenced by MHRA are not authorised for self-administration. They are intramuscular injections intended for administration by a healthcare professional, as stated in the patient information leaflet. There may be situations where these products are prescribed to a patient to be self-administered, after appropriate training, but this will be a decision taken by the prescriber based on local clinical guidelines/policies. You may wish to contact your GP or NHS Trust for further information on this. As stated above, NICE have made a recommendation for research on self-administration of Vitamin B12 injections to inform future guidance on this subject.

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/>