



Medicines & Healthcare products
Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00986**

22 September 2026

Dea [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 2 September 2026.
You wrote:

I request the following recorded information under the Freedom of Information Act 2000 concerning oral ivermectin tablets for human use.

1. Historical UK authorisations

Please provide details of any UK marketing authorisation (MA) or historic product licence for oral ivermectin tablets granted before PL 23218/0227 on 11 April 2023, including:

- * product name and strength;*
- * licence number and holder;*
- * date and legal basis of authorisation; and*
- * current status or date of withdrawal.*

Please specifically confirm whether Stromectol 3 mg Tablets, Mectizan or any other oral ivermectin tablet was ever authorised in the UK before 11 April 2023.

2. Current UK reference medicinal product

Please provide any record held by MHRA identifying a UK-authorised ivermectin 3 mg tablet currently eligible to be cited as the reference medicinal product (RMP) for a new UK-wide generic application under Regulation 51B.

If MHRA does not designate or maintain a list of such products, please confirm whether MHRA records identify any currently eligible UK RMP for ivermectin 3 mg tablets.

For each currently authorised generic or hybrid ivermectin tablet, please also provide:

- * the legal basis of the application;*
- * the RMP cited;*
- * its MA number, holder, country or UK territory and initial authorisation date; and*
- * the identity and authorised market from which the bioequivalence (BE) comparator*

was sourced.

Please distinguish between the legal RMP and the comparator used in the BE study.

3. PL 40546/0266 and PL 40546/0267

The published SmPCs identify the following products, held by Aristo Pharma GmbH, as first authorised on 5 August 2026:

- * Ivermectin 3 mg Tablets - PL 40546/0266; and*
- * Ivermectin 6 mg Tablets - PL 40546/0267.*

For each product, please provide:

- * the legal basis and application type;*
- * the regulatory procedure or assessment route;*
- * the original submission and validation dates;*
- * whether any transitional arrangements relating to applications submitted by 31 December 2024 applied;*
- * the cited RMP and BE comparator, if it was a generic or hybrid application;*
- * whether it was an informed-consent or duplicate application and, if so, the product name and PL number of the source or parent authorisation; and*
- * whether the 6 mg strength was supported by a separate BE study or an additional-strength biowaiver.*

Please also provide the Public Assessment Reports for these two authorisations or confirm when they are expected to be published.

I am not requesting commercially confidential dossier contents. Where information is withheld, please provide the remaining non-exempt information and identify the applicable exemption.

If necessary to remain within the cost limit, please prioritise section 3, followed by confirmation of whether any oral ivermectin tablet was authorised in the UK before 11 April 2023.

MHRA Response

Please see our responses to each of your questions below.

1. Historical UK authorisations

We have no record of an ivermectin oral medicine being granted a marketing authorisation before Ivermectin 3mg Tablets (PL 23218/0227) on 11 April 2023.

We have no record of a medicinal product called "Stromectol 3mg Tablets" or "Mectizan" being granted marketing authorisations in the UK.

2. Current UK reference medicinal product

Please note that the purpose of an FOI request is to confirm whether we hold information and consider that information for release, on request. We cannot advise on suitable reference products or requirements for applications through an FOI request. Please contact the Regulatory Information Service (RIS): RIS.NA@mhra.gov.uk, for information on suitable reference products and requirements for applications in the UK. Alternatively, you may wish

to request a scientific advice meeting if you think this would be helpful. Further information on how to do this is available on our website:

<https://www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra>

3. PL 40546/0266 and PL 40546/0267

Ivermectin 3 mg tablets (PL 40546/0266) and Ivermectin 6 mg tablets (PL 40546/0267) were granted marketing authorisations on 05 August 2026. These were national abridged complex applications, submitted under HMR Regulation 54 (which is equivalent to Article 10a, i.e. well-established use applications). The applications were received by MHRA on 28 November 2025 and were validated on 01 December 2025.

We are currently preparing the Public Assessment Report (PAR) for these marketing authorisations, and this will be published in the next 6-8 weeks. For this reason, we are exempting the release of PAR under Section 22 (information intended for future publication). The use of this exemption requires that we consider the public interest.

We recognise that there is an interest in this PAR and that release of the information would be of benefit in general to show transparency in MHRA's day-to-day work for the public to see how MHRA has considered these medicinal products to be authorised for use. We also recognise that in exceptional circumstances it is beneficial for MHRA to publish relevant assessment reports as soon as possible, such as in the event of a major safety finding or regulatory anomaly. Neither of these circumstances apply in this case.

We also recognise that to release a copy of the PAR for a medicinal product when it has not been finalised can risk that the information in that PAR in draft form could be misinterpreted by the reader, if it contains incomplete information on the licensing process or product. Furthermore, to release a version of the PAR in draft form would harm relations with the marketing authorisation holder, who is typically given an opportunity to comment on a PAR before it is published.

On balance MHRA is satisfied that in this instance the public interest in maintaining the exemption outweighs the public interest in disclosure. Therefore, the information you seek will not be released at this time.

We can advise that the PAR will be published on the MHRA Products Portal in the next 6-8 weeks. A link to the MHRA Products Portal is provided below:

<https://products.mhra.gov.uk/>

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/>