



Medicines & Healthcare products
Regulatory Agency

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Our Ref: **FOI2026/00141**

10 March 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 11 February 2026. You wrote:

"Please can you provide the data provided in Marketing Authorisation which supports the clinical assessment for Promazine 2.5 and 5mg/5ml (PL 40546/0178-0179) MAH Aristo Pharma GmbH.

We are particularly interested in the request made from the CHM for the clinical package and how this was addressed by the MAH or Modules 2.5 in order to satisfy the WEU legal basis."

MHRA Response

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We noticed that the product names of these medicines are incorrect in the request. The correct product names are Promazine 25 mg/5 ml and 50 mg/5 ml Oral Solution (PL 40546/0178 – 0179; MAH Aristo Pharma GmbH).

We confirm that we hold the information you have asked for. However, we consider that some of the information you have requested is commercially sensitive and is therefore exempt from release under Sections 43(1), 43(2) (S43 – Commercial interests) of the FOIA.

In response to your request, we are providing the following documents:

- **Clinical Overview.**

Please note that some redactions have been applied to these documents under the Section 40(2) (S40 – Personal information) and Section 41(1) (S41 – Information provided in confidence) of the FOIA.

We will explain these exemptions below.

Section 40:

(2) Information is exempt information if it contains elements of personal data, the disclosure of which would be unfair in that it would breach the first principle of the Data Protection Act which says that information must be processed fairly and lawfully.

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).

Section 43 is a qualified exemption and requires that we consider the public interest.

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 all information available in these documents would be of benefit in general to show transparency in MHRA's day-to-day work for the public to see to see the details of the CHM advice given and the information provided by the marketing authorisation holder to address that enabled MHRA to consider this medicinal product to be acceptable for use.

Considerations in favour of withholding the information

The information provided by the marketing authorisation holder (MAH) to address the advice given by CHM is commercially sensitive information that has been provided to MHRA in confidence. The MAH has spent time and resources in developing their product in order to meet the regulatory guidelines. This information can be used by rival companies in developing their own products, thus overcoming regulatory hurdles at the expense of the marketing authorisation holder.

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

We have published the assessment of Promazine 25 mg/5 ml and 50 mg/5 ml Oral Solution (PL 40546/0178 – 0179), please see the link below to the Public Assessment Reports (PAR) that is available on the MHRA website for this product:

[Public Assessment Report](#)

This concludes our response to your request.

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/>