Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00114**

25 March 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 3 February. You wrote:

> *We would like to request copies of the below documents related to the reclassifications of famotidine 10mg / Pepcid AC (Famotidine 10mg; PL 00025/0312 (Merck, Sharp & Dohme Limited, Hoddesdon, UK) from;*
>
> *a) a POM to P medicine (1994)*
>
> *and from;*
>
> *b) a P to GSL medicine (2000)*
>
> *Requested documents:*
>
> *1) Copies of the reclassification submission documents (redacted if necessary)*
> *2) Copies of the assessors' report (redacted if necessary)*
> *3) Associated Annexes to the report*
> *4) Stakeholder comments to the reclassification (or summary of these if appropriate)*
> *5) Copies of any educational materials approved with either of these switch applications*

MHRA Response

We can confirm that the Agency holds the information you are seeking.

However, the information you have requested is commercially sensitive and is therefore exempt from release under Section 43(2) of the FoI Act.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category.

In this instance we feel that the release of this information could undermine the commercial interests of the intellectual property holder by providing an advantage to competitors.

As required by the FoI Act the use of this exemption requires the public interest for and against disclosure to be assessed.

We recognise that there is a public interest in the disclosure of commercial information, however, in this case the information to be withheld relates to detailed aspects of the Chemistry, Manufacturing and Controls (CMC), this information could provide a decisive advantage to competitors in the pharmaceutical manufacturing space, while considering in parallel that the information does not carry strong factors in the public interest:

- the Marketing Authorisation for this product was cancelled in 2008, and
- there has been no known event concerning a public health matter related to the cancelled authorisation and no known procedural issue where the public would seek further information or debate.

However, when considering arguments against disclosure as described above, on balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

Section 40(2)

We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

Please note, some of the redactions relate to handwriting due to a risk that a person/s could be identified from their handwriting style. However, for certain redactions where the information is useful for example to navigate or better understand the information released we have converted the handwriting to typed text below:

- page 367 redaction reads ‘ Change in legal status from POM to P.
- page 371 redaction reads:

Number of Volumes	2	Number of Pages	581
Number of Volumes	1	Number of Pages	22
Number of Volumes	13	Number of Pages	36126

Advice and assistance

We wish to inform you of the below:

- The assessment predates the current legislative framework established under the Human Medicines Regulations 2012, Regulation 62, and instead reflects the previous environment in which:
    - The Medicines (Products Other than Veterinary Drugs) (General Sales List Order) 1984, and
    - The Medicines (Sale and Supply) (Miscellaneous Provisions) Regulations 1980 were amended to permit P/GSL supply at that time.
- It was also an era when a *single licence could hold multiple legal statuses*, which is no longer possible under the current legislative system.

We would also mention that during the handling of the request it became apparent that due to the extent of material, the administrative work involved approached the threshold of a burden that was unlikely to be justified. Therefore, if making new requests for reclassifications please kindly limit such a request to a single reclassification procedure.

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/