Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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MHRA Website

Our Ref: **FOI2026/00496**

22 May 2026

Dea[redacted]

Thank you for your Freedom of Information (FOI) request received on 6 May 2026. You wrote:

> *I am writing to make a request under the Freedom of Information Act 2000.*
> *Please provide copies of any assessment reports, scientific evaluation reports, or other internal decision documents prepared by the MHRA in connection with the granting of the following UK marketing authorisations:*
> *• PLGB 41042/0088*
> *• PLGB 41042/0089*
> *In particular, I kindly request disclosure of any documents relating to:*
>
> *1. The scientific or regulatory assessment undertaken by MHRA when granting these marketing authorisations, including any available assessment reports or summaries, whether full or abbreviated.*
> *2. The assessment and approval of any extensions or variations to these marketing authorisations relating to the extension of therapeutic indications.*
> *3. Any consideration given by MHRA, in connection with the above authorisations or subsequent indication extensions, to the applicability of an extension of the market protection period to eleven years under the Human Medicines Regulations 2012 (as amended).*
> *If any of the requested information is held in multiple documents, please provide all documents that fall within the scope of this request. If any information cannot be disclosed, I would be grateful if you could specify the relevant exemption under the Freedom of Information Act and provide any non-confidential portions that can be released.*

MHRA Response

We can confirm that the Agency holds the information you are seeking. However, we are engaging an exemption from disclosure under Section 22(1) of FOI Act as the information is intended for publication at a future date, when we publish our Public Assessment Report (PAR) for these marketing authorisations.

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

We recognise that there is an interest in this assessment report 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/