Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00453**

21 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 24 April 2026. You wrote:

> *Lundbeck has the above PIP approved in 2023 (MHRA-100515-PIP01-22-M01 (update) | MHRA*
>
> *Please let me know if a marketing authorisation application for extending it for paed use has been submitted by Lundbeck or will be submitted and when is the tentative approval date in the UK?*

MHRA Response
We can confirm that no marketing authorisation application has been granted to extend Brintellix 10, 15 or 20 mg film-coated tablets (PLGB 00458/0296-298), or for Brintellix 20 mg/ml oral drops solution (PLGB 00458/0299), for use in children.

Regarding whether there are any pending applications with MHRA to extend these medicinal products for use in children, we refuse to confirm or deny we hold this information under Section 41(2) (S41 – information provided in confidence) and Section 43(3) (S43 – prejudice to commercial interests) of the FOIA.

We will explain these exemptions below.

Section 41 –
(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with Section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.

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).
(3) The duty to confirm or deny does not arise if, or to the extent that, compliance with Section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the "neither confirm nor deny" provision for a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. 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 saying whether information is held or not. 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 confirming whether or not we hold the information
To confirm or deny whether or not an application has been received by MHRA would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients. It would also be of benefit in general to show transparency in MHRA's day-to-day work for the public to see what applications are currently being considered by MHRA.

Considerations in favour of neither confirming nor denying whether we hold the information
To confirm or deny whether we have received an application for use of a particular medicine for a specific indication would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is being considered by MHRA can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to confirm or deny that we may hold any information on applications that are not yet authorised in the UK can make companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for UK patients.

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/