Medicines & Healthcare products Regulatory Agency

[redacted]

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

foi.request@mhra.gov.uk.

MHRA Website

Our Ref: **FOI2026/00423**

24 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 20 April 2026. You wrote:

> *We are writing to request copies of Module 2.4 (Nonclinical Overview), Module 2.5 (Clinical Overview), and Module 5 (Clinical Study Reports) for Sertraline 50 mg and 100 mg film-coated tablets (PL 20416/0214-0215), which are currently held by Crescent Pharma Limited.*
>
> *The licence was transferred following a change of ownership from Rx Pharma (previous Licence No. PL 18869/0022). Upon review of our records, we note that we do not hold these documents as approved by the MHRA.*
>
> *To ensure our records remain complete and compliant with the approved dossier, we kindly request copies of the authorised Module 2.4, Module 2.5, and Module 5 (Clinical Study Reports) for this product.*

MHRA Response

Under Section 14(1) of the FOI Act, public authorities are not obliged to comply with a request which is deemed vexatious. By way of clarification, it is the request which is treated as vexatious not the person making the request.

A request may be treated as vexatious if the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on the agency.

A vexatious request is assessed with reference to all the circumstances of an individual case. There are four broad themes to consider when looking at whether FOI requests are vexatious.
These four themes are:

1. the burden (on the public authority and its staff);
2. the motive (of the requester);
3. the value or serious purpose (of the request); and
4. any harassment or distress (of and to staff).

These four broad themes are not a checklist, and they are not exhaustive they simply emphasise that a range of factors need to be considered when apply Section 14(1).

In this case, the Agency is treating your request as vexatious because we are already working on an FOI request from yourself (FOI2026/00377), which we have not yet completed our response. The burden that would be placed on MHRA and its staff in fulfilling both this request and FOI2026/00377 in their entirety (we are permitted to aggregate requests from the same organisation) triggers Section 14. In order to fulfil both requests, staff would be required to locate the documents listed in your requests, which cover two separate medicinal products. We would then need to go through each set of documents page by page to see if any information in those documents needs to be redacted under sections of the FOI Act. We would be required to consult with two separate marketing authorisation holders, who may ask for additional information in those documents to be withheld under sections of the FOI Act that we would need to consider.

Across the products where you have asked for this information, this would place a disproportionate burden on staff to meet your request. Therefore, on this basis, the Agency has decided that Section 14(1) of the FOI Act applies on this occasion.

We request that you wait until we have responded to FOI2026/00377 before submitting any further 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/