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: **FOI2025/01067**

28 October 2025

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 1 October 2025. You wrote:

> *Further to your letter we would like to then request the Bio Equivalence Summary Tables for the following :-*
>
> *Bedranol 160 mg sustained release capsules (PL 4416/0068)*
> *Beta Prograne 160 mg Sustained Release Capsules (PL 10686/0001)*

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 organisation.

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 an FOI request(s) is 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 for the following reasons:

The marketing authorisation for Bedranol 160 mg sustained release capsules (PL 4416/0068) was granted to Sandoz Limited on 07 July 1988. The marketing authorisation for Beta

Prograne 160 mg Sustained Release Capsules (PL 10686/0001) was granted to Tillomed Laboratories Limited on 04 July 1991.

In order to fulfil this request in its entirety, we would need to search for the clinical documents for two separate medicinal products (which due to their age would require a search of both electronic and paper records). We would then need to look through any clinical documents we hold for each product to see if we hold any bioequivalence studies. We would then need to liaise with two separate marketing authorisation holders on the release of the bioequivalence study tables.

We estimate that the work itemised above would place a disproportionate burden on staff in order to meet your request in its entirety. Therefore, on this basis, the Agency has decided that Section 14(1) of the FOIA applies on this occasion.

We ask if you can please limit your request to one particular medicinal product, including the PL number, that you would like this information on.

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