Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref:
FOI2026/00605
FOI2026/00606

02 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) requests received on 07 and 08 June. You wrote:

FOI2026/00605:

> *Please provide the full, unredacted statistical values for the Peak Plasma Concentration (Cmax) and the Time to Peak Concentration (Tmax) achieved during the original bioequivalence cross-over trials for both PL 20117/0270 and PL 00289/2116, including the raw numerical data showing the individual participant variances (ranges) rather than just the averaged mathematical mean.*

FOI2026/00606:

> *What specific patient cohorts were used to establish the bioequivalence data for PL 2011/0270 (Morningside) and PL 00289/2116 (Teva)*

MHRA Response

We are unable to deal with your FoI request without clarification of the information you seek. This is because there are a variety of data within the bioequivalence study reports that could be interpreted as being relevant to your request, so we would like to ensure that we are sending you the precise data that you require.

Under Section 16 of the FoI Act we should assist you in helping you focus your request.

Bioequivalence studies are designed to assess whether a test product (e.g. a new generic medicine) and a reference product (e.g. the original product) behave in the same way in the body. This is done by comparing the concentration of the active substance present in the bloodstream over time which allows assessment of both the rate and extent of absorption.

These studies are usually conducted in healthy volunteers and often use a “crossover” design. This means that each volunteer receives both products being compared, one after the other, with a break (known as a washout period) in between.

This approach is used because, by giving both treatments to the same individual, differences between people (such as metabolism or body composition) are eliminated as a source of

variability. Since the same person receives both treatments under similar conditions, any differences observed are more likely to be due to the medicines themselves rather than individual differences.

For the above two studies we hold the baseline corrected maximum concentration (Cmax) and time to maximum concentration (Tmax) values for each participant, for the test product and for the reference product. We also hold the pharmacokinetic parameter ratios for Cmax (and Tmax for PL 20117/0270) i.e. the test/reference product values for each participant.

Please note that it is difficult to make direct comparisons between separate bioequivalence studies, as they are conducted using different protocols and different groups of study participants. Comparing pharmacokinetic data for the test product for the two different studies, for example, would be unlikely to enable any meaningful or reliable conclusions to be drawn.

Given the above information, you may wish to narrow the scope of your request to any of the following:

PL 20117/0270:

- *Baseline Corrected Liothyronine Pharmacokinetic Parameters for the Test Formulation (A)*
  This includes Cmax and Tmax values for each participant
- *Baseline Corrected Liothyronine Pharmacokinetic Parameters for the Reference Formulation (B)*
  This includes Cmax and Tmax for each participant
- *Baseline Corrected Liothyronine Pharmacokinetic Parameters Comparison Between the Test (A) and the Reference (B)*
  This includes the test/reference ratios for Cmax and Tmax for each participant.

PL 00289/2116:

- *Individual and Mean Pharmacokinetic Parameters of Baseline corrected Total (bound+free) of Liothyronine for Test (T)*
  This includes Cmax and Tmax for each participant
- *Individual and Mean Pharmacokinetic Parameters of Baseline corrected Total (bound+free) of Liothyronine for Reference (R)*
  This includes Cmax and Tmax for each participant
- *Cmax (ng/mL) - Analysis Data of Baseline corrected Total (bound+free) of Liothyronine*
  This includes the test/reference ratios for Cmax for each participant (please note that the equivalent data for Tmax has not been presented in this report).

For request FOI2026/00606 regarding patient cohorts, please note that the bioequivalence studies for PL 20117/0270 and PL 00289/2116 were conducted in healthy adult volunteers rather than patients. If you wish to know more information about the study participants, you could request the study inclusion/exclusion criteria (which describes the criteria for eligibility into the study) and/or the table of demographics/baseline characteristics of the study participants.

We will consider any revised request in line with the FOI Act.

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.

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