Medicines & Healthcare products Regulatory Agency

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

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00865**

3 September 2026

Dear [redacted]

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

> *Dear Madam or Sir,*
> *I would like to request the following information under the Freedom of Information Act (FOIA):*
> *Could you please kindly provide me with the information on whether the variations presented in the attached document have been approved by the MHRA for the following drug products:*
> *Lantus 100 units/ml solution for injection in a vial (PLGB 04425/0814)*
> *Lantus 100 units/ml solution for injection in a cartridge (PLGB 04425/0815)*
> *Lantus SoloStar 100 units/ml solution for injection in a prefilled pen (PLGB 04425/0816)*
> *MAH of the drug products is Aventis Pharma Limited (trading as Sanofi).*
> *The approval dates for EU drug product Lantus (EMEA/H/C/000284) from the EMA homepage are provided to give an approximative understanding of the timelines.*
>
> *Thanks in advance and with best regards,*
> [redacted]

MHRA Response

With regards to the "safety variation" C.I.11.z, which was granted in July 2023, this was a worksharing procedure (WS/2491), which was added to the marketing authorisations in your enquiry wording above on 16 November 2023.

With regards to the remaining variations, these concern the quality parts of the dossier and so any further information on these is exempt under Section 41(1) and Section 43(2) of the FOI Act.

Section 41:

(1) Information is exempt information if — (a) it was obtained by the public authority from any other person (including another public authority), and, (b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.

Section 43:

(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).

Section 41(1) of the FOI Act is engaged because the dates that information concerning quality variations assessed by MHRA would have been granted is information that if released would be an actionable breach of confidence.

Section 43(2) of the FOI Act concerns commercially sensitive information, in other words information that would likely/definitely cause commercial harm, if released. Engaging this section of the FOI Act requires that we consider the public interest. We have considered the public interest, including the argument for releasing the requested information (such as keeping the public informed of changes to marketing authorsations). However, we cannot see any public interest argument for release that outweighs the harm caused by releasing information concerning if and when specific quality changes to specific marketing authorisations were made.

Any changes to Module 3 of the eCTD dossier should be submitted to MHRA in a timely manner, in line with the current guidance and regulations.

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