



Medicines & Healthcare products
Regulatory Agency

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

foi.request@mhra.gov.uk

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2024/00726**

21 January 2025

Dear [REDACTED]

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

We would kindly like to request the following document under the Freedom of Information (FOI) Act concerning Hemgenix 1x10¹³ genome copies/mL concentrate for solution for infusion, PLGB 15036/0160:

Current available electronic copy - PSUR, periodic safety update report (PBRER)

MHRA Response

We can confirm that the MHRA holds a copy of the requested PSUR. Please find the requested documents attached to the email.

Information that has been redacted is exempt under Section 40 (Personal Information) or Section 43 (Commercial Interests) of the Freedom of Information (FOI) Act and is therefore withheld. Section 40 provides that personal information may be exempt from release where to do so would contravene data protection principles. Section 43 provides that information will be exempt from release where to do so would or would be likely to prejudice commercial interests. Furthermore, we do not believe that there is an overriding public interest in disclosing the redacted information in this instance.

We hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

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

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>