Medicines & Healthcare products Regulatory Agency

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[redacted]

Email: [redacted]

06 March 2024

[redacted]

FOI 24/140: Request for access to documents for Leucomax (molgramostim) - UK/H/0031/001

Thank you for your email, dated 07 February 2024, in which you requested the scientific assessment related to nonclinical toxicology as well as the reference safety information (the last version only) provided in the MAA (Marketing Authorisation Application) for Leucomax (UK/H/0031/001).

The Marketing Authorisation for Leucomax Injection 0.555 million IRU (50 mcg) (PL 00201/0149; UK/H/003/001/DC) was granted in the UK to [redacted] on 23 October 1992, concurrent with other strengths of the product, following a Decentralised procedure (UK/H/0031/001-006/DC), with the UK as the Reference Member State and Austria, Belgium, Germany, Denmark, Greece, Spain, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, and Portugal as Concerned Member States. The Marketing Authorisation for Leucomax Injection 0.555 million IRU (50 mcg), did not undergo a renewal procedure and was subsequently cancelled.

We have searched our paper and electronic records and have not found the requested scientific assessment related to nonclinical toxicology submitted in the MAA for Leucomax Injection 0.555 million IRU (50 mcg). Therefore, having exhausted all the usual avenues in our search for this information, we have concluded that it is no longer on our systems in a retrievable form.

Concerning your request for the last version of the reference safety information for Leucomax Injection 0.555 million IRU (50 mcg), we are providing you with the approved Product Summary (Summary of Product Characteristics) at the time the Marketing Authorisation was cancelled. Please note that the documentation is historical and variation

applications for other strengths of the product were submitted subsequently to update their product information.

We trust that you will find this information of use. If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

or in writing to:

Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF.

Yours sincerely,

The FOI Team,
Healthcare Quality and Access.