

RE: FOI 24/042 Request for access to documents for Leucomax (molgramostim) - UK/H/0031/001

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Mon 05/02/2024 14:57

To

Cc:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Dear

Thank you very much for coming back to me. I've spoken with the team who have been handling your request, and I can explain that the request became delayed due to the number of different searches that will need to be carried out to ensure that we've determined all the information that may be relevant. The FOIA has a 'limit' for the time that can be spent on locating and retrieving information for a request, and I am sorry that we did not come back to you sooner when the extent of these searches was realised.

We appreciate your interest in the information, so below I will explain why we need to apply an exemption to your request in its current wording and scope; I will then explain how, if you would be happy to 'narrow' this scope in the first instance, you could proceed with a smaller request.

We will need to refuse your request at this stage because the time that we need to conduct searches to locate all information that may be relevant, would exceed the 'appropriate limit' in section 12(1) of the FOIA. This is set at 24 hours. I will first explain the searches we have conducted for the information requested: 'the scientific assessment by MHRA and/other national competent authorities (if available) as well as those parts of the clinical and nonclinical documentation' for for Leucomax (molgramostim) powder and solvent for solution for injection (UK/H/0031/001.'

We have searched our electronic records which consist of files within two systems, Sentinel and Documentum, as well as team folders. Leucomax (molgramostim) powder and solvent for solution for injection (UK/H/0031/001; PL 00201/0149) was part of a collection PL 00201/0149-00201/0153. Hence the electronic search has included the search of the Sentinel and Documentum records of each member of the collection.

We have also searched across further Documentum records across several sub-folders including historical and committee papers, CSM minutes and papers and Biologicals and CSM sub-committee folders.

These searches have identified relevant parts of the initial assessment reports that you are interested in; however, the clinical and non-clinical overviews are not held in the electronic records we have viewed to date, and to fully comply with your request and determine if these are held, we would need to request searches of paper records held in archive. Additionally, to confirm that we have located all information for your request, we would need to further search Documentum over different time periods.

In addition to the time already spent, these additional searches will exceed the appropriate limit.

To move forward and assist, we can advise that a way to proceed would be to narrow your request to **those parts of the assessment report that we have identified in our searches to date**. We will then be able to process this as a new request for a smaller amount of information.

While this formally closes your request, I do hope that our suggestion about a way forward will be useful for you.

I look forward to hearing from you.

Yours sincerely

[REDACTED]

Freedom of Information Manager
MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: [REDACTED]
Sent: Friday, February 2, 2024 3:00 PM
To: [REDACTED]
Cc: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>; [REDACTED]
Subject: SV: FOI 24/042 Request for access to documents for Leucomax (molgramostim) - UK/H/0031/001

You don't often get email from [REDACTED]

Dear [REDACTED]

Thank you very much for your email below. Would it be possible for you to estimate when we could expect to receive the requested information and the type of information you are expecting to provide? This would be very helpful for the planning of our project activities. We are eagerly awaiting the information.

Wishing you a pleasant weekend.

With kind regards

Fra: Lander, Lou <Lou.Lander@mhra.gov.uk>

Sendt: 1. februar 2024 21:05

Til: [REDACTED]

Cc: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Emne: FOI 24/042 Request for access to documents for Leucomax (molgramostim) - UK/H/0031/001

Dear [REDACTED]

When we wrote to you to acknowledge your request for information, which we had received on 3 January 2024, we advised you that we would issue our response within 20 working days.

I am writing to advise that we have not been able to meet this time frame on this occasion, and I apologise for this delay. I will write to you again to provide a revised time frame for issuing the response; you are also welcome to contact me with any queries.

Once again, I am sorry for the delay and any inconvenience caused.

Yours sincerely

[REDACTED]