Medicines & Healthcare products
Regulatory Agency

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London
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United Kingdom
**gov.uk/mhra**

[redacted]

**28 May 2024**

MHRA reference FOI2024/00063

Dear [redacted],

Thank you for your information request, which we received on 26 April. You asked for:

> *"I am writing to you under the Freedom of Information Act 2000 to request certain information and documents, detailed below, relating to UK Marketing Authorisation No. PL 43252/0030.*
>
> *That Marketing Authorisation was issued in respect of Leustat(r) (cladribine) in 1995 and the product was indicated for the treatment of hairy cell leukaemia. I have been unable to find a Public Assessment Report (or similar document) relating to this product online.*
>
> *I therefore request that the following document or response be provided:*
> 1. *The Public Assessment Report (or similar) for PL 43252/0030.*
> 2. *If this is not available, then confirmation of the clinical trials referenced by Marketing Authorisation No. PL 43252/0030."*

**MHRA response**
We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

**1. The Public Assessment Report (or similar for PL 43252/0030)**
The Marketing Authorisation for Leustat Injection (PL 43252/0030) was granted to Atnahs Pharma UK Limited on 16 February 2022, following a Change of Authorisation procedure (CoA) of Leustat Injection (PL 00242/0232; Janssen-Cilag

Limited), which was granted following a CoA procedure of the initial Marketing Authorisation, Leustat Injection (PL 00076/0170).

Leustat Injection (PL 00076/0170) was authorised to Cilag Limited on 13 October 1994. As the initial marketing authorisation pre-dates when the UK would have been required to publish a Public Assessment Report (PAR) for a new marketing authorisation, no PAR was prepared or published for this product.

**2. If this is not available, then confirmation of the clinical trials referenced by Marketing Authorisation No. PL 43252/0030.**

The marketing Authorisation for Leustat Injection was initially granted for the primary or secondary treatment of patients with Hairy Cell Leukaemia (HCL). Leustat Injection was additionally approved for the treatment of patients with B-cell chronic lymphocytic leukaemia (CLL) who have not responded to, or whose disease has progressed during or after, treatment with at least one standard alkylating-agent-containing regimen, following approval of a variation application for Leustat Injection (PL 00242/0232) on 09 February 1998. We confirm that we hold the information you have asked for. In response to your request, we are providing the attached:

(i) MHRA clinical assessment report for the initial application for Leustat Injection (PL 00076/0170) and the responses to requests for further information arising from the assessment report.

(ii) MHRA clinical assessment report for the variation application submitted to support the inclusion of the second indication (CLL) for Leustat Injection (PL 00242/0232). This was a 'roll back' variation (from a medically targeted abridged application for Leustat Injection 1mg/ml; PL 00242/0338) for the CLL indication.

Please note all points raised during assessment of the applications were resolved satisfactorily, prior to approval.

We consider that some information is exempt from disclosure. Under section 17(1) of the FOIA, when we refuse any part of the requested information, we must specify the relevant exemption and explain why the exemption applies.

Redactions have been made under the following Sections of the FOIA:

**Section 40** – Disclosure of information subject to Section 40 would be an infringement of personal data. Section 40 is an absolute exemption, and no consideration of the public interest is required.

**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.

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**Section 43 –**

(1) Information is exempt information if it constitutes a trade secret.
(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).

**Public interest test**
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

**Considerations in favour of releasing the information**
To release this information would benefit in general by showing transparency in MHRA's day-to-day work for the public to see assessment reports produced by MHRA in an unredacted form.

**Considerations in favour withholding the information**
The information concerning third parties who are involved in the product development would be of great interest to rival companies who may want to know the relationships between the marketing authorisation holder and third parties named in the assessment reports. This can be used to the commercial benefit of rival companies to the detriment of the marketing authorisation holder.

The information concerning references in the assessment report can be used by rival companies in developing their own clinical overviews for similar marketing authorisation applications, thus overcoming regulatory hurdles at the expense of the marketing authorisation holder.

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are given below.

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Yours sincerely,

Healthcare, Quality and Access Group
**Medicines and Healthcare products Regulatory Agency**

**Appeal rights**

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: 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

**Re-use of our information**

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

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