Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00687**

23 July 2026

Dea[redacted]

Thank you for your Freedom of Information (FOI) request received on 26 June 2026. You wrote:

> *Dear Sir/Madam,*
>
> *I would be grateful if you could provide the following information*
> *1. The complete regulatory history of Chlorphenamine 2 mg/5 ml Oral Solution (PL 51463/0142) from Kent pharma ,*
> *2. A copy of the Public Assessment Report (PAR) for PL 51463/0142, if available.*
> *3. Details of the legal basis / regulatory route under which this product was granted (for example, Article 10(1), 10(a), 10(3), or any other applicable article).*
> *4. Confirmation as to whether PL 51463/0142,was granted following a Change of Ownership /Change of Authorisation Holder, and if so, a brief summary of the licence history, including:*
> - *Previous PL numbers (if applicable)*
> - *Dates of transfer*
> - *Names of former and current Authorisation Holders*

MHRA Response

Please note that the marketing authorisation for Chlorphenamine 2mg/5ml Oral Solution (PL 51463/0142) was granted to Kent Pharma UK Limited on 14 February 2023 following a Change of Authorisation holder (CoA) application. In the licence history for this specific marketing authorisation, the following non-confidential updates/variations were granted:

- A renewal application was granted on 28 November 2025
- Type IA variations were granted on 15 May 2023 and 13 December 2023 to update the Pharmacovigilance System (PhVS).
- Updates to the PhVS were granted on 08 June 2023, 06 February 2024, 01 March 2024 and 15 July 2026
- Sunset Clause notifications were granted on 29 August 2024 and 27 August 2025
- A Type IB variation to amend the SmPC was granted on 15 November 2024

The original marketing authorisation for this product was granted to Dalkeith Laboratories Limited on 19 September 2017 (PL 17496/0025). A link to the Public Assessment Report (PAR) for this marketing authorisation is provided below:
https://mhraproducts4853.blob.core.windows.net/docs/896e74c7d5865caca3f5ceae965a80402c508571

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.

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