



## Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of  
Information Team  
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00098**

26 February 2025

Dear [REDACTED],

Thank you for your Freedom of Information (FOI) request received on 5 February 2025. You wrote:

*We would like to request a copy of the Public Assessment report (UK PAR) and information if its Initial application of the following product under the Freedom of Information Act (FOIA) of MHRA.*

*This product has been discontinued in UK. We would like to know if the product Lasix 40mg Tablets was authorized through a DCP route where UK was included with the Procedure? We tried to search this but could not get any information about it in the public domain.*

*Product name: Lasix 40mg Tablets  
Date of 1st Authorization: March 1965*

*MAH name:*

*Aventis Pharma Limited  
410 Thames Valley Park Drive  
Reading, Berkshire RG6 1PT, UK  
Trading as:  
Sanofi Genzyme  
410 Thames Valley Park Drive  
Reading, Berkshire RG6 1PT, UK*

*PL number: Not available*

### MHRA Response

There is one product that matches closest to the information provided above, Lasix 40 mg Tablets (PL 13402/0038), which was granted by a Change of Authorisation holder (CoA) to Aventis Pharma Limited (which was then Hoechst Marion Roussel Limited) on 16 December 1997. The original marketing authorisation for this product was granted to Hoechst UK Limited as a product licence of right (PLR 00086/5011), which means it was approved on the basis that the product was marketed before the UK Medicines Act came into force.

This licence was then converted into a reviewed product licence on 18 December 1989 (PL 00086/5011R), wherein suitable data would have been provided by the marketing authorisation holder to satisfy the regulatory requirements of the agency.

As the original authorisation of this product predates when MHRA would have been required to prepare a PAR, no PAR has been published for this product.

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

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### **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](mailto: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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