



Medicines & Healthcare products  
Regulatory Agency

MHRA Central Freedom of  
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[MHRA Website](#)

Our Ref: **FOI2025/00669**

31 July 2025

Dear [REDACTED],

Thank you for your Freedom of Information (Fol) request received on 2 July. You wrote:

*I am writing to request information under the Freedom of Information Act 2000 regarding the following UK marketing authorisations:*

1. PL 00057/0934
2. PL 00057/0935
3. PL 03194/0051

*We are interested in obtaining Module 2 documentation specifically for the diluent component of these MAs. We are requesting: 3.2.P- part, 2.4, 2.5 & 2.7*

*The objective of this request is to understand the regulatory basis for the diluent used in these products, including its safety, quality, and pharmacological justification. This information will support our regulatory due diligence exercise and contribute to internal planning aligned with UK regulatory standards for sterile injectable products.*

## **MHRA Response**

The Agency has completed its search for the information you have requested and we are able to confirm that we do not hold the information you have requested.

Bacteriostatic Water for Injections (PL 00057/0934; Pfizer Limited) was granted a Marketing Authorisation on 29 March 2012, following a change of ownership from PL 00032/0193; which was granted a Marketing Authorisation to Upjohn Limited on 15 March 1994.

The Marketing Authorisation for PL 00032/0193 was granted as an abridged standard application.

Brevinor 0.5 milligram (mg) /35 micrograms (µg) Tablets (PL 00057/0935; Pfizer Limited) was granted a Marketing Authorisation on 15 February 2012, following two changes of ownerships from PL 00032/0398, which was granted a Marketing Authorisation to Pharmacia Limited on 27 June 2002 and, prior to this from PL 08821/0037 which was granted a Marketing Authorisation to Monsanto PLC on 17 April 1996.

The Marketing Authorisation for PL 08821/0037 was granted as a simple abridged application, cross referring to the Marketing Authorisation for Brevinor Tablets PL 00286/0054R.

Diluent for GHRH Ferring (PL 03194/0051; Ferring Pharmaceuticals Limited) was granted a Marketing Authorisation on 19 April 1995. The Marketing Authorisation for PL 03194/0051 was granted according to Article 4.8(a)(i) of Directive 65/65/EEC (as amended), cross referring to the Marketing Authorisation for Somatobiss Diluent (PL 10379/0002) which was granted to Pharma-Bissendorf Peptide GMBH on 10 February 1992.

Despite a thorough search of our electronic records, including a search for the products in our database which details what we hold in the paper archives, we have been unable to locate any Module 2 documentation for the above products.

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