Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00796**

20 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 22 July 2026. You wrote:

> *Based on the information provided in FOI2025/0103 and FOI2026/00662, we understand that Rosemont product PL00427/0222 was approved through a Marketing Authorisation (MA) transfer from Broflex Syrup, held by Bioglan Laboratories Limited (PL 00041/0029).*
>
> *We also understand that Broflex Syrup held by Bioglan Laboratories Limited (PL 00041/0029) was approved as a "piggyback" abridged simple application, using Broflex Syrup held by Bio-Medical Services Limited, York (PL 04532/0001) as the reference product.*
>
> *We would appreciate clarification on the regulatory status of Broflex Syrup held by Bio-Medical Services Limited, York (PL 04532/0001). Specifically:*
> *1. Was this product authorised as the original (innovator) product supported by a full dossier, including complete quality, non-clinical, and clinical data?*
> *2. If not, was it itself authorised by reference to another medicinal product?*
> *3. If it was authorised by reference to another product, please provide details of the original authorised product for Trihexyphenidyl Syrup 5 mg/5 mL (First approved product for Trihexyphenidyl Syrup).*
> *4. Please also provide the regulatory authorisation history between the original authorised Trihexyphenidyl Syrup 5 mg/5 mL product and Broflex Syrup held by Bio-Medical Services Limited, York (PL 04532/0001), including any relevant changes in ownership, licensing, or marketing authorisation transfers.*

MHRA Response
Please see below our response to each of your questions below.

We would appreciate clarification on the regulatory status of Broflex Syrup held by Bio-Medical Services Limited, York (PL 04532/0001). Specifically:
1. Was this product authorised as the original (innovator) product supported by a full dossier, including complete quality, non-clinical, and clinical data?
2. If not, was it itself authorised by reference to another medicinal product?

As we have stated in our response to FOI2026/00662, we have searched our records and cannot find what the legal basis was for Broflex Syrup held by Bio-Medical Services Limited,

York (PL 04532/0001), so we cannot answer if this was granted as an innovator product or authorised "by reference to another medicinal product."

3. If it was authorised by reference to another product, please provide details of the original authorised product for Trihexyphenidyl Syrup 5 mg/5 mL (First approved product for Trihexyphenidyl Syrup).
4. Please also provide the regulatory authorisation history between the original authorised Trihexyphenidyl Syrup 5 mg/5 mL product and Broflex Syrup held by Bio-Medical Services Limited, York (PL 04532/0001), including any relevant changes in ownership, licensing, or marketing authorisation transfers.

The only marketing authorisation that we can locate with the product name trihexyphenidyl syrup was granted to Rosemont Pharmaceuticals Limited following a Change of Authorisation holder (CoA) application that was granted on 07 November 2012 (PL 00427/0222). This had previously been granted by a CoA to Alliance Pharmaceuticals Limited on 30 June 1999, as Broflex Syrup 5mg/5ml (PL 16853/0023). This had previously been granted to Bioglan Laboratories Limited as an abridged simple application on 27 March 1991 (PL 00041/0029).

Please note that the purpose of an FOI request is to confirm whether we hold information and consider that information for release, on request. We cannot advise on suitable reference products or requirements for applications through an FOI request. Please contact the Regulatory Information Service (RIS): RIS.NA@mhra.gov.uk, for information on suitable reference products and requirements for applications in the UK. Alternatively, you may wish to request a scientific advice meeting if you think this would be helpful. Further information on how to do this is available on our website:
https://www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra

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.

Re-use of our information