Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00276**

1 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 9 March 2026. You wrote:

> *The request was to gain clarity on the UK reference product used for the approved Biosimilar product, GOBIVAZ 100 mg solution for injection in pre-filled syringe (PL 56734/0027).*
>
> *The outcome stated that the product, Simponi 100mg Solution for Injection in a prefilled syringe, was grandfathered. However, when searching the licence number provided (PLGB 00242/0658), the search lists this as the pre-filled pen product, as opposed to the pre-filled syringe presentation.*
>
> *As the purpose of the request was to clarify the pre-filled syringe reference product used – please could you kindly confirm this?*

MHRA Response
The reference product stated for GOBIVAZ 100 mg solution for injection in pre-filled syringe (PL 56734/0027) is Simponi 100mg solution for injection in a prefilled syringe that was authorised by the European Medicines Agency (EMA) on 01 October 2009 (EU/1/09/546/007).

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,

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
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/