Medicines & Healthcare products Regulatory Agency

[redacted]

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

foi.request@mhra.gov.uk.

MHRA Website

Our Ref: **FOI2025/00872**

11 September 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 19 August. You wrote:

> *We are submitting a request under the Freedom of Information Act (FOIA) to get the Public Assessment Reports (PARs) of the below products for which marketing authorizations have been granted recently.*
>
> 1. *Isosorbide mononitrate 10mg, 20 mg, 40 mg Tablets (Angitate)*
> 2. *Carbocisteine 375 mg Capsules*
> 3. *Nortriptyline 10 mg, 25mg Tablets*
>
> *From the available Public Assessment Reports (PARs) on the MHRA products site, we have identified the RLDs used for the comparative studies for the granted MAs as presented below. However, we are currently unable to source these RLDs as these are discontinued from the market.*
>
> *RLD*
> *Elantan 40 mg (Isosorbide mononitrate)*
> *Mucodyne 375mg Capsules (Carbocisteine)*
> *Nortriptyline 10 mg, 25 mg tablets*
> *King Pharmaceuticals Ltd*
>
> *We kindly request you to provide the Public Assessment Reports (PARs) of the requested products for which marketing authorizations have been granted recently.*

MHRA Response

We are unable to deal with your FoI request without clarification of the information you seek. The reason for this is multiple marketing authorisations exist for the requested product names.

Under Section 16 of the FoI Act we should assist you in helping you focus your request. To help us do so, we would like to know the PL number/s for each marketing authorisation you intend to request a public assessment report (PAR) for.

Please note that, we publish scientific assessment reports called a Public Assessment Report (PAR) available for new marketing authorisations granted after 30 October 2005.

PARs are available on the MHRA product portal:
MHRA Products | Home

The filter on the left-hand side of the above webpage can be used to isolate results for PARs.

For requests related to reference products please consider contacting the **Regulatory information service (RIS)**

"RIS acts as the single main point of contact for marketing authorisation holders of medicines and their representatives. If you cannot find the information you need on the website, email us in the first instance to ensure your request is appropriately handled"

Source: Contact the MHRA - GOV.UK

We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

We recommend that you familiarise yourself with the Information Commissioners Office guidance on how to submit an FOI to a public authority. We have provided these links below to aid in future requests:

https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/

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