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: **FOI2024/00771**
FOI2024/00772
FOI2024/00779
FOI2024/00782

7 January 2025

Dear [redacted],

Thank you for your Freedom of Information (FOI) requests received on 6 and 10 December 2024. You wrote for each of these requests:

FOI2024/00771

"Information requested details Case Title Module 2 sections Enquiry Description PL 44041/0139, Ramipril 1.25mg Capsules, PL 44041/0140 Ramipril 2.5mg Capsules, PL 44041/0141, Ramipril 5mg Capsules, PL 44041/0142 Ramipril 10mg Capsules Noumed Under the FOI I would like to request module 2 documents for the above 4 MAs. This includes 2.3.P.1-quality overall summary, 2.4.P-non clinical overview, 2.5.P- clinical overview, 2.7.P- clinical summary"

FOI2024/00772

"I would like to request the inspection report:
Insp GMP 17907/13988-0036
UK GMP 49804 Insp GMP 49804/18421385-0001[H]
UK GMP 31201 Insp GMP 31201/349094-0012[H]
UK GMP 17543 Insp GMP 17543/13361605-0002[H]

The Clinical and Non-clinical overviews for Orobalin 1mg Film-Coated Tablets (Cyanocobalamin) PL 48259/0045"

FOI2024/00779

"I would like to request,

The Clinical and Non-clinical overviews for

Phenoxymethylpenicillin 500 mg Film-coated tablets PL 25298/0376

Amoxicillin 500mg/5ml Powder for oral suspension 48468/0017

Senease Eighteen Years Los 7.5mg Tablets PL 36722/0124

Spironolactone 12.5mg Tablets PL 12762/0544

Amoxicillin 1000mg Dispersible Tablets PL 36722/0079

Nebivolol 1.25 mg Tablets PL 25258/0312
Nebivolol 2.5mg Tablets PL-25258-0002, PL-25258-0003

Docusol Paediatric 12.5 mg/5 ml Oral Solution PL 00551/0007

Docusate Sodium Paediatric 12.5mg/5ml Oral Solution PL 00551/0007

Docusate Sodium Adult 50mg/5ml Oral Solution PL 00551/0006

Docusate Sodium 100mg/5ml oral solution PL 42176/0024"

FOI2024/00782

"I would like to request Clinical and Non Clinical Documents related to following PL;

PL 32256/0044
PL 10972/0028
PL 12762/0537
PL 30684/0304-05
PL 20117/0394
PL 20117/0384
PL 20117/0346 & 0349-0350"

MHRA Response

Under Section 14(1) of the FOI Act (FOIA), public authorities are not obliged to comply with a request which is deemed vexatious. By way of clarification, it is the request which is treated as vexatious not the person making the request.

A request may be treated as vexatious if the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on the agency.

A vexatious request is assessed with reference to all the circumstances of an individual case. There are four broad themes to consider when looking at whether FOI requests are vexatious. These four themes are:

1. the burden (on the public authority and its staff);
2. the motive (of the requester);
3. the value or serious purpose (of the request); and
4. any harassment or distress (of and to staff).

These four broad themes are not a checklist, and they are not exhaustive they simply emphasise that a range of factors need to be considered when apply Section 14(1).

In this case, the Agency is treating your request as vexatious because of the burden that would be placed on MHRA and its staff in fulfilling all these requests in their entirety. In order to fulfil all of these requests, staff would be required to locate all of the documents listed in your requests, which cover at least 20 different products. We would then need to go through each of these documents page by page to see if any information in those documents needs to be redacted under sections of the FOIA. For the overviews and non-clinical/clinical documents, we would be required to consult with the respective marketing authorisation holders, who may ask for additional information in those documents to be withheld under sections of the FOIA that we would need to consider.

Across the range of products where you have asked for this information, this would place a disproportionate burden on staff to meet your request. Therefore, on this basis, the Agency has decided that Section 14(1) of the FOIA applies on this occasion.

We request that you reduce the scope of your request, such as requesting no more than 10 inspection reports or requesting the overviews for one specific marketing authorisation only.

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 Contact Information or telephone 0303 123 1113.

Re-use of our information