



# Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of  
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00134**

7 March 2025

Dear [REDACTED],

Thank you for your Freedom of Information (Fol) request received on 7 February. You wrote:

*This is a freedom of information request for you to provide copies of the following:*

*all correspondence within the Medical and Healthcare products Regulatory Agency (MHRA);  
all correspondence between the MHRA and the Advertising Standards Authority;  
all correspondence between the MHRA and Lyma Life Ltd; and  
any documents,*

*in each instance in relation to Lyma Life Ltd's products, the Lyma Laser and Lyma Laser Pro.*

## **MHRA Response**

We can confirm that the Agency holds the information you are seeking.

However, we are withholding the information requested as we believe it is exempt under Section 43(2) and under Section 30 (1) of the Fol Act.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category.

Section 30 (1) exempts information if it has at any time been held by the authority for the purpose of -

(a) any investigation which the public authority has a duty to conduct with a view to it being ascertained -

- (i) whether a person should be charged with an offence, or
- (ii) whether a person charged with an offence is guilty of it

As such, we've concluded that the release of this information could prejudice the commercial interests of the organisation or individual that owns that documentation.

### **Public interest test**

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

### **Considerations in favour of releasing the information**

To release all information available in these documents would be of benefit in general to show transparency in MHRA's day-to-day work for the public to see how MHRA has considered different aspects of pharmacovigilance system used by the marketing authorisation holders (MAH) to determine whether they comply with pharmacovigilance obligations established within the UK.

### **Considerations in favour of withholding the information**

We recognise that there is a public interest in the disclosure of commercial information relating to the supply chain (sites involved in the manufacture and distribution) for medicines. However, when considering arguments against disclosure, there is a great interest to rival companies who are manufacturing, marketing or looking to market their own rival products. Knowledge of a supply chain and commercial arrangements with third parties can help rival companies in being able to source their active ingredient, excipients and services from these sources.

We also believe that maintaining the integrity of our ongoing investigation and mitigating the risk of reduced compliance from the manufacturer and our stakeholders outweigh the public interest. Therefore, we feel it is necessary to refrain from releasing the information until the investigation is concluded.

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.

### **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/>