



Medicines & Healthcare products  
Regulatory Agency

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

[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk).

[MHRA Website](#)

Our Ref: **FOI2026/00425**

29 April 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 21 April. You wrote:

*Please provide a copy of the "User Reference Guide: Individual Case Safety Reports (ICSRs) Submissions" as described in <https://mhrainspectorate.blog.gov.uk/2022/08/03/decommission-of-esusar/>*

*Please provide the information in email or similar format*

*If it is not possible to provide the information requested due to the information exceeding the cost of compliance limits identified in Section 12, please provide advice and assistance, under the Section 16 obligations of the Act, as to how I can refine my request.*

*If you can identify any ways that my request could be refined I would be grateful for any further advice and assistance.*

*If you have any queries please don't hesitate to contact me via email and I will be very happy to clarify what I am asking for and discuss the request.*

## **MHRA Response**

We confirm that we hold the information you have requested and provide it as an attached PDF file.

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**

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>