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: **FOI2024/00597**

30 October 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 2 October. You wrote:

> *I am writing to request information under the Freedom of Information Act 2000 regarding the use of the ChemoCare software system in the prescription and administration of chemotherapy drugs. Specifically, I am seeking information related to adverse incidents reported through the Yellow Card Scheme.*
>
> *1. Total number of adverse incidents. The total number of adverse incidents involving the ChemoCare system reported through the Yellow Card Scheme over the past five years. This should include any issues related to errors in prescription, administration, or software functionality.*
> *2. Summary of adverse incident themes including issues relating to ChemoCare*
> *3. Details of any regulatory actions, safety alerts, or warnings issued by the MHRA regarding ChemoCare, particularly those related to incidents reported through the Yellow Card Scheme.*

MHRA Response

Following a search of our database, we can confirm that the MHRA doesn't hold any adverse incident reports involving the ChemoCare system reported through the Yellow Card Scheme. We performed a search of our database for reports coded with the device name of 'ChemoCare' as well as searching for the Global Medical Device Nomenclature Collective Term 'software' and a search based upon the device name in the free text narrative fields.

Therefore, we are unable to provide a summary of adverse incident themes including issues relating to ChemoCare.

We can also confirm that the MHRA have not issued any regulatory actions, safety alerts, or warnings regarding ChemoCare.
Please be aware that any alerts or warnings issued by the MHRA can be found on our website: Alerts, recalls and safety information: drugs and medical devices - GOV.UK (www.gov.uk). This information is publicly available. Information on our Yellow Card database system is also publicly available and can be accessed here: What is being reported | Making medicines and medical devices safer (mhra.gov.uk).

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
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