Medicines & Healthcare products
Regulatory Agency

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Canary Wharf
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E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

29 May 2024

MHRA reference: **FOI2024/00150**

Dear [redacted] ,

Thank you for your information request, which we received on **25 May**. You asked for:

"Under the Freedom of Information Act will you please let me have urgently within the prescribed period of twenty working days:

* *1.The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for AMLODOPINE*

* *2 The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for RAMAPRIL*

* *.The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for DOXAZOSINE*

* *.The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for DOLTEPARIN*

* *The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for ENOXOPARIN*

I would very much appreciate it if you will treat this request as URGENT and hasten the process in any way you are able to do so."

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We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold the information you have asked for; however, this information is available to you as it is published on the MHRA's Yellow Card website.

Section 21 of the FOIA applies when the information is already reasonably accessible the requester and we do not need to provide a copy of the information; the links to access this information are here:

Amlodipine - https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000134668079.zip&agency=MHRA
Ramapril - https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000370170873.zip&agency=MHRA
Doxazosine - https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000815009573.zip&agency=MHRA
Dalteparin - https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000694851345.zip&agency=MHRA
Enoxoparin - https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000437029876.zip&agency=MHRA

When using the Interactive Drug Analysis Profile, you should remember that:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the data in the Interactive Drug Analysis Profile. This is because we have limited information about how many people have taken the medicine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse drug reaction. The existence of an adverse drug reaction report in the Interactive Drug Analysis Profile does not necessarily mean that the medicine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse drug reaction. Sometimes reactions can be part of the condition being treated rather than being caused by a medicine.
- Many factors have to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different medicines by comparing the numbers presented in the Interactive Drug Analysis Profiles. Reporting rates can be influenced by many factors including the seriousness of the adverse drug reactions, their ease of recognition and the extent of use of a particular product. Reporting can also be stimulated by promotion and publicity about a product.

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This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk.

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Safety and Surveillance Group

Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Re-use of our information

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