

FOI 23/717

Dear

Thank you for your FOI request dated 27th September 2023.

“When did the MHRA first become aware of the link between statins and myasthenia gravis?”

The MHRA utilises a variety of sources in our continuous monitoring of the safety and effectiveness of medicines and medical devices, including from our network of international regulators. Following the United Kingdom’s exit from the European Union, the MHRA are proactively monitoring safety signals raised in the European Medicine Agency’s (EMA’s) Pharmacovigilance Risk Assessment Committee (PRAC) agenda published each month. This is to ensure that the MHRA are aware of any ongoing or potential safety issues and are in a position to take action.

In August 2022 the MHRA became aware that the PRAC was assessing a potential link between statins and myasthenia gravis. In February 2023 the EMA published the PRAC recommendation for new warnings on the risk of new onset or aggravation of pre-existing myasthenia gravis with all statins. The findings of this review were considered by the MHRA’s Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM), which agreed with the recommendations. In reviewing this issue, the PEAG recommended that the MHRA inform healthcare professionals and patients of the newly identified risk. To raise awareness of this risk/corresponding Product Information updates a Drug Safety Update article was published in September 2023 (Drug Safety Update volume 17, issue 2: September 2023: 1.)

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

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*T, Medicines and Healthcare products Regulatory Agency, (via this email address).
After that, if you remain dissatisfied, you may ask the Information Commissioner at:*

*The Information Commissioner's Office
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