Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

21 May 2024

MHRA reference: **FOI2024/00069**

Dear [redacted],

Thank you for your information request, which we received on **24 April**. We have dealt with your request under the Freedom of Information Act 2000 (FOIA).
We have provided our responses to your questions beneath each question that you asked.

1. *"Is the PMCPA in any way affiliated with MHRA or the DHSC?"*

Our response
We confirm that we hold the information you have asked for; however, this information is available to you as it is published, the MHRA Blue Guide outlines in full detail how MHRA works with PMCPA. See in particular chapters 1 (Introduction), 3 (Legislative Framework), 4 (General Rules) and 10 (Self-Regulation).

We therefore engage Section 21 of the FOIA which applies when the information is already reasonably accessible to the requester and we do not need to provide a copy of the information; the weblink is given in the text above.

In addition to the above, under Section 1(1)(a) of the FOIA, we confirm this information is not held—we do not hold information about DHSC affiliations.

2. *"Have there been any rulings against Pfizer by MHRA or other government bodies in the past five years?"*

Our response
There have been no rulings against Pfizer under Part 14 (Advertising) of the Human Medicines Regulations in the past 5 years. Completed MHRA advertising investigations are published on gov.uk

Please note that 'rulings' is a fairly ambiguous term, there are many forms of regulatory actions which could be interpreted as 'rulings', for example, the suspension of a Marketing Authorisation on grounds of an inadequate demonstration of safety or efficacy, the suspension of a Good Manufacturing Practice status due to a site failing an inspection. There can also be legal rulings for example related to a product's market or data exclusivity period. If you wish to make a new request using an alternative more specific term the option is available to you, if you intend to do so, we first suggest contacting info@mhra.gov.uk to help structure such a request prior to submitting formally under FOI.

In terms of the second limb of your question, under Section 1(1)(a) we confirm that we do not hold information about other government bodies.

3. *"Would MHRA or any other government body have any remit on pharmaceutical companies bringing an industry into disrepute?"*

Our response
The Blue Guide outlines in full detail how MHRA oversees pharmaceutical industry compliance under Part 14 (Advertising) of the Human Medicines Regulations. See in particular chapters 1, 3, 4, 8 (Role of the MHRA) and 9 (Statutory Action). We therefore engage Section 21 of the FOIA which applies when the information is already reasonably accessible to the requester and we do not need to provide a copy of the information; the weblink is given in our response to question 1.

In terms of the second limb of your question, under Section 1(1)(a) of the FOIA we confirm that we do not hold information about other government bodies.

4. *Would MHRA or any government body react in any way to a pharmaceutical company making misleading or incomplete claims regarding an approved medical product? How about a product awaiting approval?"*

Our response
The Blue Guide outlines in full detail how complaints may be investigated regarding the promotion of a medicinal product howsoever licensed. See in particular chapters 2 (How to Complain), 4, 8 and 9. We therefore engage Section 21 of the FOIA which applies when the information is already reasonably accessible the requester and we do not need to provide a copy of the information; the weblink is given in our response to question 1.

As with above responses, in terms of the second limb of your question, under Section 1(1)(a) we confirm that we do not hold information about other government bodies.

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,

Healthcare, Quality and Access 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

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