Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
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United Kingdom
gov.uk/mhra

[redacted]

27 October 2023

FOI 23/726

Dear [redacted]

Thank you for your FOI request of 29 September 2023. We reproduce this in full below, included the paragraph of background information that you also provided with the request:

Background

[redacted]

My FOIA Requests

Please tell me

1. What criteria the MHRA are using, or will use, to determine when “self regulation fails”. If the MHRA have not established any criteria to determine whether self-regulation of the UK pharmaceutical industry is failing then please state this clearly in your response.

2. If such criteria do exist and one of these criteria is a failure to investigate, and arrive at a decision about, complaints in a timely manner, or within a reasonable time period (or some similar wording) please tell me what time period is considered by the MHRA to be reasonable or timely ? [Please bear in mind that the PMCPA is currently taking over a year to deal with any complaint whereas the MHRA have stated that they themselves will attempt to deal with any complaint, that they are investigating, within 30 days]

Thank you for your help with this matter. Please can you send me the information that I have requested, electronically, to this email address within the statutory 20 days.

We have dealt with your request under the provisions of the Freedom of Information Act (FOIA); the FOIA grants access to the recorded information held by public authorities.

Response to your request: question 1

This question first identifies the 'criteria' you seek as being the criteria used by the MHRA to determine "*when self regulation fails*". This is in reference to the Memorandum of Understanding (MOU) between the MHRA, PMCPA and ABPI. We reproduce the relevant part of the MOU here:

2 The MHRA deals with complaints received from whatever source that relate to matters covered by UK legislation in a timely and fair manner. This might include, with the complainant's agreement, referral to an appropriate statutory regulator, such as the Office of Communications (OFCOM), or self regulatory systems such as the PMCPA, PAGB, and Advertising Standards Authority (ASA). The MHRA will routinely decline to investigate cases where it is aware that these are under investigation by a self regulatory body but reserves the right to take action if serious public health concerns are raised or if self regulation fails.

The reference to "*if self-regulation fails*" in the MOU between the MHRA, PMCPA and ABPI refers to a failure by a pharmaceutical company to uphold high standards of information provision through the self-regulatory framework underpinned by the ABPI Code of Practice.

We do not hold a list or set of "criteria" that specify when such a failure has occurred against the ABPI Code, and therefore under section 1(1)(a) of the FOIA, we do not hold this information. This is because such instances are determined on a case-by-case basis.

To assist, we can explain that MHRA is obliged to consider any complaints made to it about the promotion of medicines in the UK as outlined in Part 14 of the Human Medicines Regulations 2012, and paragraph 2 of the MOU, provided above, describes the MHRA's role here in support of self-regulation.

While it is not the "criteria" specified in your request, we do hold some information related to the role of the MHRA which may be of interest to you. This provides examples of the circumstances when the MHRA may proceed to take statutory action against potential breaches of the above Regulations. Our Statutory

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Procedures guidance gives this explanation of the process and Section 3.3 includes the examples:

1 Introduction

1.1 The advertising and promotion of medicines is controlled by statutory measures, enforced by the licensing authority. Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916 - "the Regulations") lays down detailed controls on the advertising and promotion of medicines.

1.2 The MHRA: considers all complaints it receives about the advertising of medicines; monitors published advertising; and assesses advertising material before issue (vetting) under certain specified circumstances, where it considers such action is necessary.

1.3 The MHRA's policy is, wherever possible, that potential breaches of the Regulations are resolved through negotiations with the company concerned. Should this fail or in serious cases—for example, where there is a safety issue and a company is uncooperative or repeatedly offends—the MHRA can resort to formal procedures laid down in Part 14 of the Regulations.

1.4 The Regulations clearly set out the powers available to the MHRA to deal with those cases that cannot be resolved satisfactorily through negotiation. The legislation contains both criminal and civil sanctions.

3 Policy

3.3 When to pursue statutory procedures

Formal procedures can be initiated **at any stage** of an advertising complaint, a pre-vetting case, or a scrutiny case. These initiations would generally be in specific circumstances, for example, where:

- the advertisement constitutes a serious risk to public health, or
- the advertiser or MAH is a persistent offender, or
- a company is uncooperative in informal negotiations, or
- the company and the MHRA are unable to resolve an issue satisfactorily

Please note, we provide this related information – which we appreciate does not meet the specific wording of your request – under our section 16 duty to assist.

We can also explain that the MHRA works closely with the PMCPA to identify serious breaches of the ABPI Code where further regulatory oversight of a pharmaceutical company by the MHRA may be necessary to ensure a company understands its statutory (and self-regulatory) responsibilities and to bring a company back into full compliance. The MHRA will consider any published case reports about serious breaches of the Code by a pharmaceutical company on their own merits, having regards to the facts of a particular investigated case.

The type of oversight that MHRA may then deploy will vary depending on the circumstances of a particular case but may, for example, include the checking of company compliance processes or the scrutiny of the quality of specific promotional or non-promotional materials in use or planned for use.

The second part of this question further identifies that the criteria you are seeking refer specifically to "*whether self-regulation of the UK pharmaceutical industry is failing*". You also ask that if there are no such criteria for this circumstance, that this is stated clearly in our response.

Regarding your reference to "*any criteria to determine whether self-regulation of the UK pharmaceutical industry is failing*" in the second part of this question, we note that this appears to apply more broadly than the specific reference to individual cases in the MOU, and refers to your own view, expressed in the "*Background*" section of your request where you have expressed your concern about "*what I perceive to be the failure of the self-regulatory system for the pharmaceutical industry in the UK*".

We confirm that we do not hold any recorded information for this part of your request; we do not hold a list or set of criteria that relate to the circumstances you have described in this second part of question 1.

Please note, to assist, the MHRA Blue Guide outlines that the MHRA works closely with other regulators and self-regulatory bodies to ensure a consistent approach so that public health and safety is not compromised. You may wish to refer to the following sections of the Blue Guide for further explanation on the role of the MHRA:

1.3 Regulation of advertising
2 How to complain
8 Role of MHRA
9 Statutory action
10 Self-regulation

https://assets.publishing.service.gov.uk/media/6012d7f2d3bf7f05b92f6cfc/BG_2020_Brexit_Final_version.pdf

Response to your request: question 2

Your second question is dependent on whether information is or is not held in response to the first question and then, if one of the criteria held is about the timeliness of complaint investigation by the PMCPA, the recorded information you ask for is "*what time period is considered by the MHRA to be reasonable or timely?"*. This is in reference to the PMCPA's investigation of complaints.

We note, the MHRA's letter to you of 27 September 2023, which you attached to your request, explained the relationship between the MHRA and the PMCPA and the arrangements for investigation of complaints made under the ABPI Code of Practice. The MHRA's letter also explained that is not possible for MHRA to define a time period for the handling of a complaint against the ABPI Code, as each complaint will be looked at by the PMCPA on the circumstances and merits of that particular case and the allegations made by the complainant in that specific case.

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For absolute clarity in response to your question under the FOIA, we confirm that we do not hold any relevant recorded information in the form of criteria regarding the timeliness of complaint investigation by the PMCPA as described in this part of your request, and we do not hold any recorded information which specifies "*what time period is considered by the MHRA to be reasonable or timely ?*" for the circumstances your request describes. Under section 1(1)(a) of the FOIA, this information is not held.

The ICO's guidance on making effective FOIA requests

In responding to this FOIA request, we also hope to provide some useful advice about making effective requests for recorded information; this is taken from the Information Commissioner's guidance for requesters, which is available on the ICO website here:

https://ico.org.uk/for-the-public/official-information/how-to-write-an-effective-request-for-information/

We draw your attention to the final three points in the ICO's *"Top tips for making making a clear request"*:

> **Protect public money**
> Gaining access to public information is your right and public bodies must respect that. However, requests do cost public bodies time and money to respond to. This is public money and we need to make sure it's spent responsibly.
> It is important that you don't submit frivolous or trivial requests.
> You should not make requests for the same information more than once, unless the information has changed a lot.
> You should not make requests as a way of 'punishing' a public body if you think they have done something wrong. If you do any of the above, the public body could consider your request 'vexatious' and refuse to action it.
>
> **Make requests, not complaints**
> Don't combine a request for information with a complaint about the public body or a comment about their actions. This could make it hard to interpret what you're requesting and you may not get a response you are happy with.
> If you have a valid complaint about the public body you should follow their complaint process or complain to the ombudsman.
>
> **Be polite**
> Do not use threatening, offensive or accusatory language.
> Do not be offensive about individual members of staff.
> The public body can refuse your request if you are.

We note that the "Background" you have provided with your request appears to contain elements of each these; you state you are dissatisfied with the letter you have previously received (in the ICO's words, *"you think they have done something wrong"* and the FOI request you have made clearly follows directly from this previous engagement on the same subject), the FOI is clearly combined with a complaint

about the MHRA and your comments about their actions, and you are highly critical about a named member of staff involved in the previous engagement.

While we have dealt with your FOI request on this occasion, we politely ask that you consider the points above when using the FOIA legislation, with a view to focusing on specific requests for recorded information, rather than including extended comment and personalised criticism of members of staff. The FOIA legislation is not an appropriate forum for the latter.

Yours sincerely

Lou Lander
Freedom of Information Manager

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Appeal rights

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

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. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Or online at:

https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/