

## FOI 23/570

Dear

Thank you for your request of 05 August 2023 under the Freedom of Information Act. You requested:

*Please provide the following information with respect to the year to 31 March 2023.*

- *How many FOIA requests were received?*
- *What % were sent the information sought, or a rejection, within 20 working days?*
  
- *How many administrative complaints were received?*
- *What % of complaints received a substantive response within 20 working days of receipt?*
  
- *How many complaints have been investigated by the PHSO in each of the past 5 years.*
  
- *How many questions were submitted by the public for consideration at MHRA Board meetings?*
- *Of these questions, how many were answered at the meetings?*
- *Of the remainder, how many were answered subsequent to the meeting?*
- *What is the target maximum response time for written answers? (at the last MHRA Board meeting it was stated as 18 days)?*
- *Where a response was sent after the meeting, what % of the responses were sent within the target response time?*
  
- *Please provide a copy of the board or executive minute, or executive instruction, recording the decision, and rationale for removing the performance metric for FOIR from the Annual Report and Accounts.*

You will be aware that there is some cross over in your first question with other requests you have submitted throughout 2023; a list of all requests received with received and response dates has recently been provided to you for the time period of the financial years 2021, 2022 and 2023. Therefore, the raw data to respond to this question has been given to you in a previous FOI response; the percentages requested can be calculated from this data. Section 21(1) applies to this part of your request, as this information is already available to you.

Information for your questions about administrative complaints and complaints investigated by the PHSO is here:

#### Administrative Complaints Data

Year	Total admin complaints	Number answered late	Average days to respond	Stage 2 cases	PHSO <sup>1</sup> enquiries	Cases answered by PHSO
2023/24 (to end May 23)	9	0 (4 due for response will be late)	12.5 (based on 2 answered)	1	0	0
2022/23	48	17	19.3	4	3	0
2021/22	32	10	23.5	3	1	0
2020/21	23	1	16	3	0	0
2019/20	19	0	12.75	1	0	0

- 9 administrative complaints in the first two months of this year - categorised according to customer's stated concern
  - 1 was an alleged problem of **commission** (1 *activity-error*)
  - 8 were alleged problems of **omission** (all were *context-unresponsive* which include 4 about delays to clinical investigation applications or amendments)
  - 1 case was upheld and 1 (the Stage 2 case) was not upheld. 7 cases are pending a reply.
- The deadline for response is 20 working days.

<sup>1</sup> Parliamentary Health Service Ombudsman. If customers remain dissatisfied after an investigation and response from the Agency's Administrative Complaints Officer (Stage 2 response), their next step is to contact the PHSO via their MP. The PHSO can only review the Agency's handling/administration.

Your questions regarding questions submitted to the Board are answered individually here:

*How many questions were submitted by the public for consideration at MHRA Board meetings?*

116 (27 in chat; 89 pre-submitted)

*Of these questions, how many were answered at the meetings?*

6 were answered at meetings

*Of the remainder, how many were answered subsequent to the meeting?*

94 have been answered after the meetings.

*What is the target maximum response time for written answers? (at the last MHRA Board meeting it was stated as 18 days)?*

18 working days.

*Where a response was sent after the meeting, what % of the responses were sent within the target response time?*

For responses sent after the meeting, 57 were sent within 18 working days, 37 were sent after 18 working days.

For the final question, *Please provide a copy of the board or executive minute, or executive instruction, recording the decision, and rationale for removing the performance metric for FOIR from the Annual Report and Accounts.*

The performance metrics have been refocussed for the 2022-23 annual report to ensure they are more relevant to our public health responsibilities and to help make them more meaningful to the reader. The development of the performance metrics was coordinated by the Delivery and Performance Committee which is an executive management committee with delegated

responsibility from the Executive Committee. The annual report was discussed and received final sign off in the Board Meeting held in public of 11 July 2023: this is available on our website at the following link:

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#previous-board-meetings-and-public-sessions>

Please scroll to 08:13 of the video when the discussion begins, and then culminates in final sign off at just after 26 mins.

To further explain, the decision was taken to remove the operational internal metrics from the report, although these are still collected and monitored internally. In recognition of the importance of transparency we have created a separate section in the performance overview part of the report on page 22 entitled “Public access – Freedom of Information requests, enquiries and complaints” which is aligned with how other ALB’s report (e.g. UKHSA 2021-22 annual report and accounts). This section and the performance metrics will be further developed over the coming year.

We will also be publishing performance data for FOI requests by year end 2023, in line with Part 8.5 of the Cabinet Office FOI Code of Practice.

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](mailto:info@mhra.gov.uk)  
Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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

Yours sincerely

**MHRA Customer Experience Centre**

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

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