RE: FOI 24/115 Freedom of information request

FOILicensing <FOILicensing@mhra.gov.uk>
Wed 27/03/2024 08:45
To [redacted]
Cc:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

6 attachments (18 MB)

2023-06-BMS-MHRA_IR-_redacted.pdf; 2023-06-GPvP 242-23473-0022 - redacted.pdf; 2023-07-Alnylam-MHRA_IR-redacted.pdf; Dr Reddys GPvP redacted.pdf; 2022-12-ROVI-MHRA_IR_CAPA_1 redacted fixed.pdf; 2023-01-Glenmark-MHRA_IR-1 redacted.pdf;

Dear [redacted],

Thank you for your FOI request dated 5 February 2024 where you asked:

> *"Details of information required: All MHRA pharmacovigilance inspection reports for the period 01 December 2022 to 01 February 2024 from any company.*
>
> *This can be restricted to those inspections with only major and/or critical findings."*

Following the conclusion of the public interest test, the outcome of which favoured release. Please find enclosed the available GPvP inspection reports for all inspections conducted by MHRA for the period *01 December 2022 to 01 February 2024*.

Please note, for one of the inspections that has taken place during the above time period and which also included an inspection report, the inspection findings are currently subject to an on-going regulatory procedure, in that the inspection has not yet been closed out. Therefore, for these inspections, the information that you have requested currently cannot be disclosed. Under the Freedom of Information Act (FOIA) the applicable exemption is section 30: "Investigations and Proceedings Conducted by Public Authorities".

We have considered the balance of the public interest when applying this exemption. The section 30 exemption is to ensure that the regulatory authority is able to carry out its statutory functions efficiently, fairly, unimpeded and confidentially. In this case I have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity) and find that premature publication of the reports could be misleading, as the findings are incomplete.

The report will be available when this procedure has reached its conclusion and you are asked to reapply at that time.

Please also note, the time period during which the regulatory procedure will be completed is uncertain as it is difficult to estimate how long a company may take until they are in a position to confirm their remedial actions have been put in place. The MHRA must then conduct a follow-up inspection to verify the satisfactory implementation of those actions.

For the reports we have provided, you will see that some information has been redacted. The relevant sections of the Freedom of Information Act are:

• **Section 40 (personal data/information)**

I can confirm that the only material we have redacted is that which concerns personal data: this information is withheld as it falls under the exemption in sections 40(2) and 40(3)(a)(i) of the FOIA, which relates to the personal data of which the applicant is not the data subject. Section 40(2) of the FOIA provides that personal data relating to other persons is exempt information if disclosure would breach the Data Protection Act 1998 (DPA). We consider that disclosure of this information is likely to breach the first data protection principle in Schedule 1 to the DPA, which relates to the fair and lawful processing of personal data. Therefore, we have concluded that this information is exempt from disclosure under section 40(2) read in conjunction with section 40(3)(a)(i) of the FOIA.

• **Section 43 (2)**

Release of all, or part of, the information would be likely to, cause harm to the third party's commercial interests.

We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity) .

Please also note, when redacting sections in the reports some section titles have been redacted, this has been done purely to ease the administrative burden. The redacted section titles in sequential order are Root Cause Analysis, Further Assessment, Corrective Action(s), Preventative Action(s).

Yours sincerely,

HQA FOI Team

Appeal rights

We trust that you will find this information of use. However, If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Copyright notice

From: [redacted]>
Sent: Monday, February 5, 2024 11:54 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/115 Freedom of information request

Dear MHRA,