

FOI 23/585

Dear

Thank you for your request under the Freedom of Information Act, we apologise for the delay in response. You initially requested:

“Please can you send me a copy of any safety impact assessments relating to that Operational Transformation Programme.”

We contacted you to seek clarification, to which you responded with:

“By "safety impact assessment", I was asking for a copy of MHRA's assessment of the impact of its Operational Transformation Programme (OTP) on MHRA's management of the safety of all items regulated by MHRA (which I understand to be medicines, medical devices and blood products). And for the avoidance of doubt, that covers all aspects of MHRA's safety management - licensing, pharmacovigilance, enforcement of relevant legislation, inspections & audits etc etc.”

Thank you for providing the above clarification. We confirm that we do not hold an assessment that matches the description you have provided.

As part of the Operational Transformation Programme, one of the main changes was creating the Safety and Surveillance function. That brought together teams across the organisation with responsibility for the safety of medicines, medical devices and blood components for transfusion into the newly created Safety and Surveillance function. In the previous organisation structure these teams had been in different divisions. However, it did not introduce any changes to processes, systems or IT packages followed and used by those newly combined teams.

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 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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