



Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
[gov.uk/mhra](https://www.gov.uk/mhra)

[REDACTED]

24 October 2023

FOI 23/647

Dear [REDACTED]

[REDACTED] you for your information request, dated 29 August 2023, where you asked for:

1. Details of any clinical investigation by the MHRA of the medical device Oxevision by Oxehealth
2. Details of all evidence provided to the MHRA, or produced by the MHRA, related to the technology Oxevision by Oxehealth (in the form of clinical papers; reports; other provided evidence)
3. If not included in the above information, or, if acquiring the above information proves to be in excess of the FOI time/costs limit:
Any form of supporting information provided to the MHRA, or produced by the MHRA, that evidences the technology Oxevision by Oxehealth works on all skin tones on the Fitzpatrick scale, in all light levels (in the form of clinical papers; reports etc).
4. Details of any reported adverse incidents related to the technology Oxevision by Oxehealth

Unfortunately, the information is exempt from release under sections:

Section 31. This exemption applies when information may relate to the exercise of our regulatory functions. Section 31 is a qualified exemption, and we are required to consider the public interest in releasing the information. Releasing the requested information would reveal details of how we approach our regulatory activities and could prejudice our ongoing and future work.

In this instance we therefore consider that the public interest is best served by maintaining the exemption and withholding the requested information, as the overriding public interest is in our ability to exercise our regulatory functions to protect public health.



Medicines & Healthcare products Regulatory Agency

Parts of the information are also exempt under:

Section 41. Information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed.

Section 44. The release of information is exempt as its disclosure is prohibited by other legislation. In this case, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

The MHRA is satisfied that the information you have requested:

- constitutes information which came to us in connection with the exercise of the Agency's functions. The MHRA has a duty of consumer protection under the Consumer Protection Act 1987 which is listed as a specified function under Schedule 14 of the Enterprise Act 2002, and receives information while exercising consumer protection functions in its role as the regulator of medicines and healthcare products.
- relates to the affairs of Oxehealth, a business which continues to exist.

On that basis we are satisfied that section 44 of FOI Act applies and the information is exempt from release.

If you have a query about the information provided, please reply to this email

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



Medicines & Healthcare products
Regulatory Agency

Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

Innovative Devices – Software and AI