



Medicines & Healthcare products  
Regulatory Agency

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13 December 2023

Dear 

**FOI 23/756 - Freedom of Information request – Sciensus (*later clarified to also include Healthcare at Home*)**

Thank you for your request for information dated 18 October 2023, where you requested:

- “1. Please can you send me copies of all the reports you have received via a) the Yellow Card scheme b) healthcare professionals and c) Sciensus concerning Sciensus in the last five years?
2. Please can you send me copies of all reports and/or investigations the MHRA has begun or completed about Sciensus in the last five years?
3. Please can you send me copies of all emails sent to or from a) Laura Squire and b) Alison Cave that contain the word Sciensus in the last 12 months?”

This was then clarified:

“Yes, my request does include and covers documentation under the former name of Sciensus within the timeframe.”

***Our response***

We confirm that we hold the information you have requested, however, we judge that some of it is exempt from release. Under points 1-3 below we will set out our responses and any exemptions which apply.

**1. Please can you send me copies of all the reports you have received via a) the Yellow Card scheme b) healthcare professionals and c) Sciensus concerning Sciensus in the last five years?**

We confirm that for parts a) and b) we hold this data however, we are unable to provide you with copies of individual reports as these are exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI Act. Supplying you with this information could lead to patient identification. Further to the use of Section 40 and 41, as outlined in our [Privacy Policy](#), the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

For parts a) and b) we would be happy to consider a new request, should you wish to make one, for a summary of the reports which we have received, without providing copies of the reports themselves.

For part c), we confirm that we have received no reports from Healthcare at Home over the last 5 years. We have received reports from Sciensus. However, we consider that these are exempt from disclosure under Section 30 (1) (b), as this information is held in relation to investigations and proceedings which we are conducting.

**2. Please can you send me copies of all reports and/or investigations the MHRA has begun or completed about Sciensus in the last five years?**

Please find attached six inspection reports from the period of time prior to the commencement of investigations and proceedings, but nonetheless falling within the last five years. In some of these reports you will see entries under the section marked 'Major findings'. Please be aware that inspectors at MHRA work closely with companies to ensure resolution of any findings from inspections. The assumption is that if the report is finalised and case folder closed, then the company have provided adequate response/s to address the finding/s. Please note, the more recent inspection reports have been exempted under Section 30 (1) (b).

Redactions have been made to the reports provided with this letter under the following Sections of the FOIA.

**Section 40**

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, or 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). As a qualified exemption, 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) .

**Section 31(1)(a)** –This section of the FOIA provides for an exemption from disclosure of information which would prejudice the prevention or detection or crime. To this end, an image has been removed from report Insp GDP 15956/18074392-0001.

There is also a seventh report also occurring in the period and prior to the investigations and proceedings. I can confirm the MHRA will consider the release of the seventh inspection report for this site, in accordance with the FOIA. However, following your request we have identified an administrative oversight which means elements of this inspection report remain that require input from an inspector before it is closed out and finalised on our internal systems. Until finalised, we consider this inspection report to be commercially sensitive, and s43(2) applies.

### **3. Please can you send me copies of all emails sent to or from a) Laura Squire and b) Alison Cave that contain the word Sciensus in the last 12 months?**

We have conducted searches of the email records of Laura Squire and Alison Cave, over the last 12 months, containing the word Sciensus. We confirm that we do hold emails in scope of your request. We judge that some are exempt from release in their entirety under Section 30 (1) (b), as this information is held in relation to investigations and proceedings which we are conducting.

However, there are a number of emails, some of which were sent to/from both Alison and Laura, some to/from just Alison and some to/from just Laura. In the attached document (FOI\_23-736-3) you will find the emails in question. There are redactions applied to a number of emails under the following exemptions:

- Section 40 (1) is applied to an email which discloses your name. We publish Freedom of Information Act responses on our website, we have redacted your name to avoid subsequently publishing it.
- Section 40 (2) of the Freedom of Information Act. The redacted information is personal data (names of members of staff), and in some cases individuals at other organisations. The disclosure would lead to the identification of individuals. The staff names withheld are those of members of staff below a certain level of seniority; this is consistent with our approach to the disclosure of staff names.

- In the second email chain which is disclosed (starting on page 2 with the email of 07/07/23 17:30) we have removed from the subject field and the email body references to a different issue that are outside the scope of your request.

Where we have referenced Section 30 (1) (b) in this response, we have considered the public interest in releasing the information requested. Our judgement is that the strongest public interest favours maintaining the exemption to protect the integrity of our investigations.

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

Or online via: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Yours sincerely

**MHRA Customer Experience Centre**  
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