



Medicines & Healthcare products Regulatory Agency

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[REDACTED]
[REDACTED]

18 January 2024

FOI **23/895**

Dear [REDACTED]

Thank you for your Freedom of Information request dated 20 November 2023.

Your request

Please send me the application for the Exceptional Use Authorisation with product code SSD-COVID19AGVCGS7 and product name SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab – Gold).

Our Response

I confirm that MHRA holds the information you requested but this is exempt from disclosure under exemptions of s40(2) FOIA personal information, s41(1) information provided in confidence and s43(1) and (2) FOIA commercial sensitive information.

Section 40(2) Personal Information

Part of the information has been withheld under s40(2) of the FOIA (personal information). This is because it contains third party personal data and the Agency is satisfied that disclosure here would breach the first data protection principle, in particular the requirement of fairness on the basis that disclosure would not be reasonably expected by the third parties.

S40(2) FOIA Personal information

[Freedom of Information Act 2000 \(legislation.gov.uk\)](https://www.legislation.gov.uk)

1. Any information to which a request for information relates is exempt information if it constitutes personal data of which the applicant is the data subject.



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2. Any information to which a request for information relates is also exempt information if—
 - a) it constitutes personal data which [F1does] not fall within subsection (1), an the first, second or third] condition below is satisfied

Section 41(1) FOIA given in confidence.

[Freedom of Information Act 2000 \(legislation.gov.uk\)](https://www.legislation.gov.uk)

Section 41(1) of the FOIA states:

(1) Information is exempt information if :

- b) It was obtained by the public authority from any other person (including another public authority), and,
- c) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person. The Information Commissioner (ICO) has provided extremely detailed guidance on when section 41(1) may be applied. We have followed this in our consideration of the information in this case.¹
- d) For the exemption to apply when information was provided to the public authority in confidence, a number of tests need to be met.

These are that:

- The information was obtained by the authority from any other individual, company, other public authority or any other type of legal entity
- The disclosure of this information would constitute a breach of confidence.

The ICO recommends that public authorities follow the test of confidence set out at the High Court of Justice in *Coco v A N Clark (Engineers) Limited* [1968] FSR 415. This test has three parts:

- whether the information has the necessary 'quality of confidence', if it is more than trivial and not otherwise accessible.
- whether it was provided to the public authority in circumstances importing an obligation of confidence, for example, where there are explicit conditions for any subsequent use or disclosure in a contractual agreement, or where the circumstances provide obvious or implicit restrictions on use¹

<https://ico.org.uk/media/for-organisations/documents/1432163/information-provided-in-confidence-section41.pdf#:~:text=Section%2041%20sets%20out%20an%20exempti>



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on%20from%20the,its%20disclosure%20would%20constitute%20a%20breach%20of%20confidence.

- whether disclosure would be an unauthorised use of the information which would be to the detriment of the confider.

For commercial information this will usually be a detriment to the confider's commercial interests.

- A 'legal person' (the individual person, company, public authority other legal entity who provided the information) could bring a court action for this breach of confidence, and
- that court action would be likely to succeed In this case, we confirm that this information was obtained by the MHRA from another person.

We consider that disclosure would constitute an actionable breach of confidence because it meets the tests above; it has the necessary quality of confidence because it is not trivial and is not otherwise accessible in the public domain, and it was imported to the MHRA with explicit conditions of confidentiality.

Disclosure in this instance would therefore be an unauthorised use of the information which would cause detriment to the third-party providing the information to use.

We will discuss the nature of this detriment in the considerations of section 43(2) below. It is therefore considered that disclosure would be an actionable breach with the likelihood that this action would succeed.

Section 43 (1) FOIA trade secrets and s43(2) FOIA commercial sensitivity

[Freedom of Information Act 2000 \(legislation.gov.uk\)](https://legislation.gov.uk)

To inform our considerations for Section 43(1) and (2) we consulted SureScreen Diagnostics to ask for their opinion on the release of the information requested. They confirmed that they consider this information to be "confidential and proprietary intended only to be shared with the Health Authority". The document contains details considered to be Trade Secrets and therefore would be likely to cause significant harm to the company and therefore is being withheld under s43(1) FOIA.

They have identified how disclosure would be likely to cause prejudice to their commercial interests, and that this would cause significant harm both financially as well as an unfair competitive advantage for competitors". This engages the section 43(1) and 43(2) exemptions.

- The ICO's guidance on section 43 explains that the FOIA does not define the term 'trade secret', but that the Commissioner refers to The Trade Secrets (Enforcement, etc.) Regulations 2018 and considers that, to be a trade secret, information should:



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- be secret, in the sense that it is not generally known among, or readily accessible to, people within the circles that normally deal with that kind of information;
- have a commercial value, because it is secret. Its disclosure should also be liable to cause real (or significant) harm to the owner or be advantageous to any rivals; and
- be subject to reasonable steps under the circumstances, taken by the owner, to keep it secret. The ICO guidance also advises that a trade secret is the property of its owner, and gives the following example of the type of information that may be a 'trade secret':

The First-tier Tribunal discussed the 'trade secret' definition in the case of the Department for Work and Pensions v IC EA/2010/0073, (20 September 2010). It quoted from previous court and Tribunal decisions which reviewed the nature of a trade secret.

The Tribunal noted that a trade secret was information, which, if disclosed to a competitor, would be liable to cause real (or significant) harm to the secret's owner. This assumed that the owner used the information in a trade or business and that they either limited the dissemination of the information or at least didn't encourage or permit its widespread publication.

The Tribunal also noted that the concept of a 'trade secret' related to a particular kind and quality of information. In terms of 'kind', it considered this suggested "something technical, unique and achieved with a degree of difficulty and investment". In terms of 'quality', the Tribunal indicated that the term 'trade secret' suggested the "highest level of secrecy".

We consider that this example is relevant in this case, and that the information requested in this case therefore falls within section 43(1).

S43(2) Commercial sensitive information

S43(2) applies where disclosure of the information would, or would be likely to, prejudice the commercial interests of any legal person (an individual, a company, the public authority itself or any other legal entity).

The ICO explains that this is a prejudice-based exemption, which means that information is exempt if its disclosure under FOIA if disclosure would, or would be likely to, prejudice the commercial interests of any legal person (including the public authority holding it).

A 'commercial interest' relates to a legal person's ability to participate competitively in a commercial activity. The ICO's guidance lists a range of circumstances in which a public authority may hold commercial information.



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Most relevant here is:

- If you undertake regulatory activity (for example, if you issue licences or accreditations), you may hold commercially sensitive information obtained in the course of your investigations or related to your functions.

For information to be exempt from disclosure under section 43(2), a public authority must be able to show that the disclosure of the information would, or would be likely to, prejudice or harm commercial interests of an individual, a company, the public authority or any other legal entity. This is known as 'the prejudice test'. In conducting this test, we need to identify what the harm is and why it may occur as a result of disclosure.

The risk of prejudice occurring must be "real and significant, more than hypothetical or remote", and we must be able to demonstrate a causal relationship between the disclosure of the information in question and the prejudice we believe will occur. It is not sufficient to simply argue that because information is 'commercially sensitive', its disclosure would, or would be likely to, prejudice commercial interests.

We appreciate there is public interest in the general principles of accountability and transparency. However, this needs to be weighed against the public interest in avoiding any unwarranted prejudice to the commercial interests of MHRA and the SureScreen Diagnostics.

On balance we do not find any significant public interest value so as to outweigh the prejudice that would be caused to the company's commercial interests in a highly competitive industry. Disclosure of the information would cause harm to the company concerned if released as the information would be copied and cause detriment and possibly increase costs to the government. We therefore consider that the public interest in maintaining the exemption outweighs the public interest in disclosure of the withheld information.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be considered again by 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

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



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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