



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00116**

21 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 4 February. You wrote:

The MHRA has approved the use of the product Syncrodin 3 mg film-coated tablets, for i.a. short-term treatment of jet-lag in adults, and treatment of insomnia in patients aged 6 to 17 years with ADHD or ASD (see PL 20243/0004).

Accordingly, we hereby make a request, under the Freedom of Information Act, to receive copies of Module 2.5 (including any addendum documents) of the Common Technical Document (CTD) in relation to the abovementioned approval.

Please do not hesitate to reach out should anything above be unclear or further information is required in order to handle the request.

As the request is urgent, a swift handling would be highly appreciated. The information can be sent to us on email.

MHRA Response

The Agency has completed its search for the information you have requested, and we are able to confirm that we do hold the information you have requested.

You will see that some information in the attached report has been redacted.

We consider that the information is exempt under sections 40 and 43 of the Fol Act.

Furthermore, some of the information redacted falls outside the scope of the Fol request.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that "Personal data shall be processed lawfully, fairly and in a transparent manner...".

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the Fol Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is

intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category. 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).

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

Re-use of our information

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>