



Medicines & Healthcare products  
Regulatory Agency

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[MHRA Website](#)

Our Ref: **FOI2026/00326**

23 April 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Foi) request received on 24 March. You wrote:

*I am writing to request information under the Freedom of Information Act regarding melatonin immediate-release tablets that are licensed in the UK  
Specifically, I would like to request: A list of all melatonin immediate-release tablet products that currently hold a valid UK Marketing Authorisation (MA)  
Please include, where available:*

- \* *Product name*
  - \* *Strength*
  - \* *Pharmaceutical form*
  - \* *Packsize*
  - \* *MA number*
  - \* *Marketing Authorisation Holder (MAH)*
  - \* *Manufacturer*
  - \* *Indication*
  - \* *License status : Active & Commercialised OR Active & not Commercialised OR Withdrawn OR SUNSET DATE - Active & Non Commercialised*
- [X]

### **MHRA Response**

We can confirm that the Agency holds this information. However, some of the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

However, to be helpful you can find the information you seek at [MHRA Products | Home](#) where the information can be retrieved.

We are also providing a PDF file which includes a list of marketing authorisations (MAs) for tablet formulations with the active substance melatonin. The PL numbers in the file can be searched on the portal given above to locate the requested information about these MAs.

- Product name; section 1 of the Summary of Product Characteristics
- Strength, often included in the product name but see also section 2 of the SmPC
- Form; section 3 of the SmPC
- Packsize/s: section 6.5 of the SmPC

- MA number section 8 of the SmPC.
- Indication/s: section 4.1 of the SmPC
- Licence status: the provided list is for granted MAs, we do not hold information on status: commercialised / non-commercialised.
- Batch release site within the EU

\*note some of the above information will also be repeated / represented in the patient information leaflet.

Please note that the manufacturing sites for medicines are typically considered exempt from release under Section 43(2) and Section 41 of the FOIA. An exception to the above is where the site of batch certification is the same as the manufacturer. There is a requirement for the marketing holder to include the site of batch certification in the patient information.

We are engaging an exemption from disclosure under Section 41(1) of the Fol Act, which protects information provided in confidence.

The information you have requested relates to details of manufacturers of medicines that include melatonin, the information was obtained by the Agency from another person and the Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information.

However, the information you have requested is also commercially sensitive and is therefore also exempt from release under Section 43(2) of the Fol Act.

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.

In this instance we feel that the release of this information could alert competitors to manufacturing sites and provide market intelligence which could be used to undercut business arrangements or by other means, would be likely to cause commercial harm.

As required by the Fol Act the use of this exemption requires the public interest for and against disclosure to be assessed.

We recognise that there is a public interest in the disclosure of commercial information relating to the public understanding which site/s are used to manufacture a specific medicine. However, we give this factor a low weight, in the circumstances, primarily as the medicines are authorised through the usual thorough regulatory process including appropriate manufacturing site certification.

## **Advice and assistance**

Regarding the last part of your request:

*“License status : Active & Commercialised OR Active & not Commercialised OR Withdrawn OR SUNSET DATE - Active & Non Commercialised [X]”*

We are not sure what exactly you are referring to; are you seeking the date of the sunset clause for the specified products, or the date these products were marketed in the UK, or both? If you wish to submit a new request for on this point, with further clarity provided to us, we will handle this as a new request.

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

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### **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](mailto: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**

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

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