Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2024/00797**

14 January 2025

Dear [redacted],

Thank you for your Freedom of Information (FOI) request received on 16 December 2024. You wrote:

> *Under the Freedom of Information Act 2000, I would like to request information about UK-based entities currently holding valid MHRA authorizations or licences that enable them to manufacture, compound, or wholesale distribute oral ketamine products. This includes both standard licensed products and "specials."*
>
> *Specifically, I request:*
>
> *1. **Compounding and Manufacturing Authorizations:***
> *- The names and addresses of manufacturers or "specials" licence holders who are authorized to prepare oral ketamine formulations. If such entities produce custom oral ketamine solutions or capsules (e.g., for hospital pharmacies, private clinics), please identify them.*
> *- Any data MHRA holds on whether these facilities compound in-house or partner with external contract manufacturing organizations. If publicly available, I would appreciate the names of external partners or their MHRA-registered details.*
>
> *2. **Dosage Forms and Strengths Approved or Notified to MHRA:***
> *- If recorded, the commonly authorized dosage strengths or formulations (e.g., oral solution strengths) that these manufacturers or compounding facilities produce.*
>
> *3. **Private Sector Involvement:***
> *- While MHRA may not track prescribing, if there is any known distinction in licensing documents between facilities supplying primarily to NHS entities versus those known to supply private clinics, please include that information.*
>
> *I understand certain commercially sensitive details may be exempt, but any publicly available licensing information or data that can help identify active compounding and manufacturing partners for oral ketamine is greatly appreciated.*

MHRA Response

With regards to Question 1 and Question 2, we can confirm that the Agency holds the information you are seeking concerning marketing authorisations.

However, the information you have requested is commercially sensitive and is, therefore, exempt from release under Section 41(1), and Section 43(1)/Section 43(2) of the FOI Act.

We will explain these exemptions below.

Section 41:
(1) Information is exempt information if — (a) it was obtained by the public authority from any other person (including another public authority), and, (b) 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.

Section 43:
(1) Information is exempt information if it constitutes a trade secret.
(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

Regarding the use of Section 41, the information you have requested was provided by marketing authorisation holders for specific ketamine products that have been authorised in the UK. As such, the Agency believes that if this information were released it would be an actionable breach of confidence. Therefore, we are not going to be releasing the requested information.

Regarding the use of Section 43, this exempts information which if disclosed would be likely to prejudice the commercial interests of any person, including a public authority. The information you seek falls into this category. In order to apply Section 43 properly, a consideration of the public interest (public interest test) is required.

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The ‘public interest’ is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The ‘right to know’ must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is ‘applicant blind’. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of releasing the information
To release this information would benefit in general by showing transparency in MHRA’s day-to-day work to the public and for the public to see all sites related to the manufacture of an authorised medicine.

Considerations in favour withholding the information
Information on the manufacturing sites used by marketing authorisation holders for their products is commercially sensitive information that has been provided to MHRA in confidence. To publish this information would be to provide competitor companies with information on where this product can be sourced, helping these companies in sourcing their own product manufacturers to the commercial detriment of the marketing authorisation holder concerned. Further, to release this information could make companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

This decision is in compliance with the Heads of Medicines Agencies/European Medicines Agency (HMA/EMA) guidance on transparency, where on pages 14 and 34 it states that manufacturers are commercially confidential information (CCI) and, therefore, are exempt from release. A link to this guidance is provided below:
HMA/EMA GUIDANCE DOCUMENT ON THE IDENTIFICATION OF COMMERCIALLY CONFIDENTIAL INFORMATION (europa.eu)

With regards to manufacturers for "Specials" licence holders, the manufacturing authorisations for these are not product specific and there is no requirement for them to notify us what product they are manufacturing. This means that we do not hold information on what product each "Specials" manufacturer actually makes, beyond that they manufacture, for example, "tablets," "oral solutions" or that they do "secondary packaging."

A link to the register of manufacturing sites for Specials is provided below:
Human and veterinary medicines: register of licensed manufacturing sites - GOV.UK

With regards to Question 3, MHRA does not track prescribing of medicines. However, we can confirm that there is no distinction in documentation required between facilities supplying the NHS versus those supplying private clinics.

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
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/