Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00850**

21 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 1 August 2026. You wrote:

> *Dear MHRA,*
>
> *Under the Freedom of Information Act 2000, I am requesting the following information about the regulation of ketamine and esketamine advertising and safety monitoring, and clarification of one entry in your 2026 medicinal-treatment-services compliance log. I am content to receive the response electronically; if any part is refused, please advise which exemption applies and release the remainder.*
>
> *1. Advertising-compliance actions since 2019.*
> *Please provide a list of all advertising-compliance actions the MHRA has taken since 1 January 2019 concerning services or products relating to ketamine or esketamine for mental-health indications (for example depression, suicidality, PTSD, anxiety), including for each:*
> *• the date of the action;*
> *• the name of the entity involved (clinic, company or individual);*
> *• the nature of the concern (for example, promotion of a prescription-only medicine to the public, misleading or exaggerated efficacy claims, or omission of safety information); and*
> *• whether the case was resolved by informal advice, an undertaking, or formal enforcement.*
> *Where the action is recorded on a published register or log, please include the reference or URL for each entry.*
>
> *2. Identification of "Infusion Therapy London (mental-health support service)."*
> *In the June 2026 medicinal-treatment-services compliance log, one entry refers to "Infusion Therapy London (mental-health support service)." Please confirm the corporate identity of the provider (company name and Companies House number, where held), and whether the entry concerns a ketamine- or esketamine-related service.*
>
> *3. Yellow Card reporting for ketamine and esketamine.*
> *Please provide the number of Yellow Card adverse-drug-reaction (ADR) reports received for (a) ketamine (racemic ketamine) and (b) esketamine (including Spravato), broken down by calendar year from 2019 to the most recent full year available. Where the data*

allows, please also indicate how many reports in each year relate to off-label use for depression or other mental-health indications, and how many relate to licensed esketamine use.

4. Coordination with the ASA and CMA.
Please confirm whether the MHRA holds any formal coordination or information-sharing arrangements with the Advertising Standards Authority or the Competition and Markets Authority specifically in relation to private ketamine or esketamine clinics, and provide any documents (for example memoranda of understanding or correspondence since January 2024) recording such arrangements.

I note the ACMD's updated review of ketamine use and harms (28 January 2026) for context.

Kind regards,

[redacted]

MHRA Response

Please see our response to each of your points below.

1. *Advertising-compliance actions since 2019*
   This information is exempt under Section 21(1) of the FOI Act, because the information is reasonably accessible to you, as it is already in the public domain. You can find this information at:
   https://www.gov.uk/government/collections/advertising-investigations-by-mhra

   You can click on the year of interest to see MHRA advertising investigations completed in that period split by month of completion.

2. *Identification of "Infusion Therapy London (mental-health support service)*
   We understand Infusion Therapy London is the company name as stated in the published summary report. The website is:
   https://www.infusiontherapylondon.com

   Information on Companies House is publicly available and, therefore, exempt under Section 21 of the FOI Act.

3. *Yellow Card reporting for ketamine and esketamine*
   Regarding your request for number of suspected adverse drug reaction (ADR) reports received for a) ketamine, and b) esketamine, broken down by calendar year, we can confirm this information is exempt under Section 21(1) of the FOI Act, because the information is reasonably accessible to you, as it is already in the public domain. The MHRA publishes reported side effects for medicines and vaccines in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed here: https://yellowcard.mhra.gov.uk/idaps .

   Please be aware that in our internal dictionary the term "esketamine" is a synonym of "ketamine s-isomer". As such, the reports for "esketamine" can be identified by searching for "ketamine s-isomer".

   When reviewing the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report to ensure that you do not misinterpret the data.

Regarding your request for number of reports relating to off-label use for depression or other mental health conditions, please be aware that reporters do not always include the term "off-label use" in the structured event fields or elsewhere in their report. Additionally, in reports where the term "off-label use" is captured in the report as an event term, it may not refer to the suspect drug of interest, because a single report may contain multiple suspect drugs.

Finally, on a Yellow Card report, the indication of a drug is not always reported since this field is not mandatory.

With consideration of the above points, the MHRA has performed searches of the available data and can confirm the below:

- A search for all UK spontaneous suspected adverse drug reaction (ADR) reports associated with ketamine and/or esketamine, from 01/01/2019 up to and including 31/05/2025 identified **194** reports.
- Of the **194** reports, **13** reports reported an event term that fell within the MedDRA dictionary Higher Level Term (HLT) "Off Label Uses"[1]. These can be viewed on the Total Reaction Profile tab via iDAPS using the link provided above.
- Of the **194** reports, **0** reports were identified where the indication for ketamine/ esketamine was a term that fell within the MedDRA dictionary HLT "Off label uses"[1].
- Of the **194** reports, **26** reports were identified where the indication for ketamine/ esketamine was a term falling within the MedDRA dictionary SOC: "Psychiatric Disorders".
- When combining the 13 reports and the 26 reports from the datasets above, **35** unique reports were identified.

Please find attached in Annex 1 a further breakdown of these reports by year of receipt and indication term for the ketamine/esketamine drug (MedDRA PT name[1]).

Please be aware that more than 1 indication can be reported for the same drug. Additionally, when considering the spontaneous data within this response, it is important to be aware of the following points:

- The number of reports received via the Yellow Card scheme does not directly equate to the number of people who experience adverse events and therefore cannot be used to determine the incidence of a reaction. Adverse event reporting rates may be influenced by multiple factors including the seriousness of adverse events and their ease of recognition.
- A reported reaction does not necessarily mean it has been caused by the drug or medical device, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a drug or medical device, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug or medical device. Underlying concurrent illnesses, a range of recognised complications or patient/user factors may be responsible and such events can be coincidental. The data provided, therefore, is not a summary of known or proven adverse reactions and must not be interpreted and used as such.
- The number of reports is accurate at the time of data extraction and minor changes in numbers can occur if the reporter provides further detail later.
- The MHRA continuously monitors the safety of medicines and medical devices through a variety of pharmacovigilance processes, including the Yellow Card

1 MedDRA (Medical Dictionary for Regulatory Activities) is a clinically validated international medical terminology dictionary. It's organised by System Organ Class (SOC), divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT) and finally into Lowest Level Terms (LLT). Further information can be found here: https://www.meddra.org/how-to-use/basics/hierarchy

scheme. As part of our signal detection processes, adverse event reports received by the Yellow Card scheme are assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

4. *Coordination with the ASA and CMA.*
   MHRA holds no documents concerning formal coordination or information sharing arrangements with either the Advertising Standards Authority or the Competition and Markets Authority specifically in relation to private ketamine or esketamine clinics.

   General information on the Advertising Groups interactions with other regulators is contained in the MHRA Blue Guide, a link to this is provided below.
   https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines

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/

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