FOI 23/101

6th March 2023

Dear

Thank you for your email.

Regarding the below questions:

1. **The number of ILAP applications made concerning products that contain psilocybin and/or psilocin.**
2. **The status of all ILAP applications made concerning products that contain psilocybin and/or psilocin.**

MHRA refuse to confirm or deny we hold this information, under Section 41 (S41 – information provided in confidence) and Section 43 (S43 – commercial interests) of the FOI Act (FOIA).

S41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. S43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm caused in releasing this information, which would constitute a breach of trust between MHRA and those companies coming to us to apply for ILAP. This breach of trust would result in fewer companies wanting to engage with MHRA in ILAP and would inhibit the good advice that we provide companies, which would be detrimental to their product development and ultimately to patients.

3. **The number of completed and ongoing clinical trials of psilocybin and/or psilocin containing products registered with the MHRA.**

Information on ongoing clinical trials is publicly available in various registries, including ISRCTN Registry and Home - ClinicalTrials.gov. You can use the advanced search functions to identify trials of interest based on the product name, condition under investigation, etc.

4. **All data held by the MHRA pertaining to the toxicology and safety profile of any psilocybin and/or psilocin containing products in healthy and clinical populations submitted to the MHRA.**

There are no authorised medicinal products in the UK containing psilocybin and/or psilocin. MHRA refuse to confirm or deny whether we hold any data from pending applications received, under Section 41 (S41 – information provided in confidence) and Section 43 (S43 – commercial interests) of the FOI Act (FOIA).

S41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. S43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and

cannot see any public interest argument that outweighs the commercial harm caused in releasing this information, which would provide competitor companies with knowledge of whether an application has been received or not and, therefore, how close such a product is to being marketed.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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 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

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