Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

17 November2023

FOI 23/828

Dear [redacted]

Mental health and psychedelics [redacted]

Thank you for your email [redacted] concerning the Licensing of psylocibin and MDMA and updates regarding the approval process for these products.

Regarding whether we have received any applications for such products, unfortunately this type of information is commercially sensitive, and we cannot confirm or deny whether we have received any applications. We consider this information to be exempt under Section 41(2) (Information provided in confidence) and Section 43(3) (Commercial interests) of the Freedom of Information (FOI) Act.

Section 41 is an absolute exemption, and no consideration of the public interest is required, except to state that we would consider confirming or denying whether we have received any applications for a particular product would be an actionable breach of confidence. Section 43 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 in alerting competitors to whether a company is close to obtaining a marketing authorisation or not. Please note that in line with the guidance from the Information Commissioner's Office (ICO) we consider a response or disclosure under FOI to be made to the world at large, which in due course will be published (in a redacted form to remove personal information) on our website. Therefore, any response or information we give to you or anyone else via FOI will become publicly available.

For this part of your enquiry, which we have refused under the FOI Act, if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk. Please remember to quote the reference number above in any future communications.

If you 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.

[redacted] may not be aware that UK medicines legislation does recognise that there are situations where a product which is not authorised in the UK may be required for an individual patient. Regulation 167 of the Human Medicines Regulations 2012 provides an exemption from the need for a marketing authorisation for a medicinal product under certain circumstances, which includes the importation of such medicines to the UK. In the interest of public health, the exemption is narrowly drawn because unlicensed medicines or “specials”, unlike licensed medicinal products, may not have been assessed by us here at the MHRA against the criteria of safety, quality and efficacy. We have published guidance about this process, which any patient can discuss further with their Doctor.

Please be aware we publish redacted FOI replies and these can be found at the following link of our website below:
https://www.gov.uk/government/collections/freedom-of-information-responses-from-the-mhra-2021

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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