FOI 23/690

Dear

Many thanks for your request for information dated 19 September 2023.

> *"I note with interest that the United States have made daridorexant a schedule VI controlled substance under the US controlled substances act.*
>
> *I also note that NICE appear to be preparing to publish a TA for the drug in October approving its use.*
>
> *With the above in mind could you please tell me if the medication in question will be classified under the misuse of drugs act 1971 and the misuse of drugs regulations 2001?*
>
> *If not would you be able to briefly outline the rationale as to why this decision was made not to classify the drug under the above act/regulations?"*

We can confirm that considerations in relation to controlled drug status are made by the Advisory Council on the Misuse of Drugs (ACMD) at the Home Office.
Advisory Council on the Misuse of Drugs - GOV.UK (www.gov.uk)

For further information regarding the controlled drug status of daridorexant, please contact ACMD directly. They can be contacted as follows:
Email: ACMD@homeoffice.gov.uk

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 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

Communications and engagement team
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