

ACMD

Advisory Council on the Misuse of Drugs

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Kit Malthouse MP
Minister of State for Crime Reduction and Policing
2 Marsham Street
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30 April 2021

Dear Minister,

RE: Sunosi

The Advisory Council on the Misuse of Drugs (ACMD) is grateful to the Medicines and Healthcare products Regulatory Agency (MHRA) for providing a written dossier and oral presentation on the medicine, "Sunosi" (active ingredient: solriamfetol), which can be prescribed to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy.

Further to these representations, the ACMD has now considered whether this drug should be subjected to control under the Misuse of Drugs Act 1971 (MDA).

The ACMD has concluded that Sunosi has a low risk of abuse potential and physical dependence potential. Routine pharmacovigilance is expected to be sufficient to monitor the risk of abuse, misuse and diversion of this drug.

There have also been no reports of abuse in the UK. MHRA officials have confirmed that there is currently no signal of drug misuse, abuse or dependence in subjects with narcolepsy, obstructive sleep apnoea (OSA), major depressive disorder (MDD), healthy volunteers, or patients with renal impairment. This is, however, considered by the MHRA as an important risk and will be monitored via the bi-annual Periodic Safety Update Reports (PSURs).

Recommendation

The ACMD therefore recommends to the Home Office that the control of Sunosi under the Misuse of Drugs Act 1971 is not required at this time.

In the event that evidence emerges to indicate the prevalence and misuse of Sunosi in the UK, the ACMD will again review the necessity of the control of this drug under the Misuse of Drugs Act 1971.

Yours sincerely,



Prof Owen Bowden-Jones
Chair of the ACMD



Prof Roger Knaggs
Chair of the ACMD's Technical Committee

CC: Rt Hon. Priti Patel MP (Home Secretary)

Rt Hon. Matt Hancock MP (Secretary of State for Health and Social Care)