ACMD

Advisory Council on the Misuse of Drugs

ACMD Chair: Prof Owen Bowden-Jones
Technical Committee Secretary: Matthew Brace
1st Floor (NE), Peel Building
2 Marsham Street
London
SW1P 4DF
ACMD@homeoffice.gov.uk

Rt Hon Chris Philp MP
Minister of State for Policing, Crime and Fire
2 Marsham Street
London
SW1P 4DF

2nd December 2022

Dear Minister,

RE: ACMD Advice on the Classification and Schedule of Remimazolam (Byfavo®)

The Advisory Council on the Misuse of Drugs (ACMD) are grateful to the Medicines and Healthcare products Regulatory Agency (MHRA) for providing a written dossier and oral presentation on the ultra-short-acting benzodiazepine remimazolam (Byfavo®). Further to these representations, the ACMD are able to provide advice regarding the appropriate Classification and Schedule for this medicine under the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001, respectively.

Byfavo® was approved for marketing by the European Commission on 26th March 2021 for use in adults for procedural sedation. Procedural sedation is required for a wide range of medical endoscopic procedures, imaging techniques and in minor surgical procedures.

Classification

As a benzodiazepine, it is likely that potential harms would be commensurate to other benzodiazepine drugs already controlled under Class C.

Recommendation 1: The ACMD recommends that remimazolam should be controlled as a Class C drug under the Misuse of Drugs Act 1971.

Lead Department: The Home Office.

Measure of implementation: Legislative change to the Misuse of Drugs Act 1971.

Scheduling

Benzodiazepines are currently either scheduled under Schedule 3 or Schedule 4 (Part 1) of the Misuse of Drugs Regulations 2001.

Remimazolam is a prescription only medicine, which can only be given by a healthcare professional experienced in sedation.

The safety profile, toxicity and behavioural effects of remimazolam are consistent with other benzodiazepines in Schedule 3. The dependence and diversion potential are consistent with other short-acting benzodiazepine drugs and is comparable to midazolam that is used for sedation in several settings and is an existing Schedule 3 drug. Midazolam has previously been recognised as a potential 'date rape' drug due to its ability to induce anterograde amnesia and fast-acting sedative effects.

However, there were several key factors considered by the ACMD that support remimazolam being placed in Schedule 4 (Part 1) as opposed to Schedule 3.

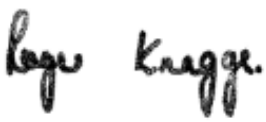
Firstly, compared to midazolam, remimazolam has a much shorter duration of action and its effects wear off within minutes. Remimazolam has a much lower oral bioavailability than midazolam and bitter taste, hence the ACMD concluded that it is much less likely to be an attractive 'date rape' drug. Furthermore, the requirement for remimazolam to be administered by a clinician in a controlled setting only for procedural sedation meant the availability of remimazolam is less than midazolam.

Recommendation 2: The ACMD recommends that remimazolam should be scheduled under Schedule 4 (Part 1) of the Misuse of Drugs Regulations 2001.

Lead Department: The Home Office.

Measure of impact: Legislative change to the Misuse of Drugs Regulations (as amended).

Yours sincerely,



Professor Owen Bowden-Jones
Chair of the ACMD

Professor Roger Knaggs
Chair of the ACMD Technical Committee