

COMMISSION TO THE ACMD – LONGER TERM REVIEW OF CANNABIS-BASED PRODUCTS FOR MEDICINAL USE IN HUMANS

Background

On 03 July, I commissioned the Advisory Council on the Misuse of Drugs ('the ACMD') to advise on part-two of the review on cannabis and cannabis related products. The commission sought the views of the ACMD on the rescheduling of cannabis under the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") and any other mitigating action to prevent the risks of misuse and diversion. The ACMD were asked to provide advice within three weeks and twelve months of the commission.

The ACMD issued their short-term advice on 19 July and 11 September with a set of recommendations for both the Home Office and the Department of Health and Social Care ('DHSC'). On 1 November, cannabis-based products for medicinal use were added to Schedule 2 under the 2001 Regulations.

The purpose of this commission is to ask the ACMD to commence the longer-term review of cannabis-based products for medicinal use.

In doing so, the ACMD should not review or consider any of the following which fall under the Misuse of Drugs Act 1971:

- a) The classification of cannabis as a Class B drug under Schedule 2, Part II;
- b) Any associated criminal offences for cannabis as summarised in Schedule 4;
- c) The cultivation of the cannabis plant under section 6(2) or the cultivation under a licence of the cannabis plant under Regulation 12 of the 2001 Regulations (irrespective of the THC content of the seed or variety of the plant).

The commission is split into three components and is as follows:

Monitoring/Assessment of the impact of the change in legislation on cannabis-based products for medicinal use

- a) As part of this review can the ACMD:
 - i. provide an outline for an assessment framework. This should set out how the ACMD will assess the various impacts of rescheduling cannabis-based products for medicinal use to Schedule 2 under the 2001 Regulations, and the data sources (including those provided by the Home Office and DHSC) the ACMD will use by **November 2019?**

- ii. Carry out an assessment of the impact of the legislative change and report its findings and any recommendations to mitigate the issues identified by **November 2020**?

Synthetic cannabinoids

The current definition of synthetic cannabinoids in the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 is provided at **Annex A**.

The ACMD provided its last report on the harms of the third-generation synthetic cannabinoids in November 2014. In the ACMD's initial advice on the short-term commission dated 19 July 2018, the ACMD recommended that synthetic cannabinoids remain in Schedule 1 of the 2001 Regulations pending their longer-term review.

On 6 November, the Minister for Policing and the Fire Service committed to asking the ACMD for a refresh of its 2014 assessment on the harms associated with synthetic cannabinoids and provide necessary advice on this issue. This follows the concerns raised by Members of Parliament and by the police and crime commissioners on the current classification of synthetic cannabinoids under the Misuse of Drugs Act 1971 ("the 1971 Act").

- a) As such, can the ACMD provide the following by **Summer 2020**?
 - i. an updated harms assessment to the ACMD's previous reports on synthetic cannabinoids.
 - ii. its recommendation on whether the current classification under the 1971 Act of synthetic cannabinoids listed in **Annex A** is appropriate.
 - a. If not appropriate, can the ACMD provide their recommendation on whether all or some synthetic cannabinoids should be reclassified under the 1971 Act?
 - b. If reclassification is recommended, can the ACMD advise on the appropriate reclassification?
 - iii. its recommendation on whether the current scheduling under the 2001 Regulations of synthetic cannabinoids listed in **Annex A** is appropriate.
 - a. If not appropriate, can the ACMD provide their recommendation on whether all or some synthetic cannabinoids should be rescheduled under the 2001 Regulations?
 - b. If rescheduling is recommended, can the ACMD advise on the appropriate rescheduling?

Cannabis-based products for medicinal use

- a) As part of the longer-term review can the ACMD provide, by **November 2020**, their full advice on:
 - i. whether the scheduling of products which currently fall under the definition of cannabis-based products for medicinal use is appropriate
 - ii. If not, can the ACMD advise on the appropriate rescheduling?
 - iii. whether any further legislative amendments regarding cannabis-based products for medicinal use are required under the 2001 Regulations.

Annex A

Listings contained in Class B under the Misuse of Drugs Act 1971 ('the 1971 Act') and Schedule 1 under the Misuse of Drugs Regulations 2001 ('the 2001 Regulations').

[[2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone

3-Dimethylheptyl-11-hydroxyhexahydrocannabinol]

[[9-Hydroxy-6-methyl-3-[5-phenylpentan-2-yl]oxy-5, 6, 6a, 7, 8, 9, 10, 10a-octahydrophenanthridin-1-yl] acetate

9-(Hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a, 7, 10, 10a-tetrahydrobenzo[c]chromen-1-ol]

Any compound structurally derived from 3-(1-naphthoyl)indole, 3-(2-naphthoyl)indole, 1H-indol-3-yl-(1-naphthyl)methane or 1H-indol-3-yl-(2-naphthyl)methane by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent.

Any compound structurally derived from 3-(1-naphthoyl)pyrrole or 3-(2-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring by alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent.

Any compound structurally derived from 1-(1-naphthylmethylene)indene or 1-(2-naphthylmethylene)indene by substitution at the 3-position of the indene ring by alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent.

Any compound structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent.]

Any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the cyclohexyl ring to any extent.]

Any compound structurally derived from 3-benzoylindole by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent.

Any compound structurally derived from 3-(1-adamantoyl)indole or 3-(2-adamantoyl)indole by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent.

Any compound structurally derived from 3-(2,2,3,3-tetramethylcyclopropylcarbonyl)indole by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent.

Any compound (not being clonitazene, etonitazene, acemetacin, atorvastatin, bazedoxifene, indometacin, losartan, olmesartan, proglumetacin, telmisartan, viminol, zafirlukast or a compound for the time being specified in sub-paragraphs (h) to (lc) above) structurally related to 1-pentyl-3-(1-naphthoyl)indole (JWH-018), in that the four sub-structures, that is to say the indole ring, the pentyl substituent, the methanone linking group and the naphthyl ring, are linked together in a similar manner, whether or not any of the sub-structures have been modified, and whether or not substituted in any of the linked sub-structures with one or more univalent substituents and, where any of the sub-structures have been modified, the modifications of the sub-structures are limited to any of the following, that is to say—

- (i) replacement of the indole ring with indane, indene, indazole, pyrrole, pyrazole, imidazole, benzimidazole, pyrrolo[2,3-b]pyridine, pyrrolo[3,2-c]pyridine or pyrazolo[3,4-b]pyridine;
- (ii) replacement of the pentyl substituent with alkyl, alkenyl, benzyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl, 2-(4-morpholinyl)ethyl or (tetrahydropyran-4-yl)methyl;
- (iii) replacement of the methanone linking group with an ethanone, carboxamide, carboxylate, methylene bridge or methine group;
- (iv) replacement of the 1-naphthyl ring with 2-naphthyl, phenyl, benzyl, adamantyl, cycloalkyl, cycloalkylmethyl, cycloalkylethyl, bicyclo[2.2.1]heptanyl, 1,2,3,4-tetrahydronaphthyl, quinolinyl, isoquinolinyl, 1-amino-1-oxopropan-2-yl, 1-hydroxy-1-oxopropan-2-yl, piperidinyl, morpholinyl, pyrrolidinyl, tetrahydropyranyl or piperazinyl.

stereoisomeric forms, salts, esters and ethers as well as preparations in paragraphs 2 to 4 of Part 2 and paragraphs 2 to 4 of Part 3 of Schedule 2 to the 1971 Act.

