# ACMD

## Advisory Council on the Misuse of Drugs

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10 March 2017

Dear Minister,

**RE: Further advice on methylphenidate-related NPS**

In February 2016, my predecessor Professor Les Iversen wrote to the then minister for Preventing Abuse, Exploitation and Crime, requesting that the Temporary Class Drug Order (TCDO) on seven methylphenidate-related Novel Psychoactive Substances be re-laid for a further 12 months.

This TCDO was re-laid until June 2017, to allow the Advisory Council on the Misuse of Drugs (ACMD) more time to collect the evidence required to provide further advice for full control under the Misuse of Drugs Act 1971. The ACMD believes that the TCDO has been effective in reducing the prevalence of these substances and that the TCDO level of control was proportionate in the interim.

I am now pleased to present to you the ACMD's further advice on this matter in the enclosed report. The ACMD's recommendation for full control applies to the seven substances currently controlled under the TCDO and extends to an additional five closely-related substances. These five similar substances have subsequently appeared on markets following the TCDO and are included in this advice due to their potential for similar harms.

Recommendation

The ACMD recommends that the following 12 substances be fully controlled under the Misuse of Drugs Act 1971 as **Class B** substances:

**Ethylphenidate**
**Methylnaphthidate ('HDMP-28')**
**Isopropylphenidate ('IPP' or 'IPPD')**
**Propylphenidate**
**4-Methylmethylphenidate**
**Ethylnaphthidate ('HDEP-28')**
***N*-Benzyl-ethylphenidate**
**3,4-Dichloroethylphenidate**
**3,4-Dichloromethylphenidate ('3,4-DCMP')**
**Methylmorphenate**
**4-Fluoromethylphenidate**
**4-Fluoroethylphenidate**

The ACMD will provide further advice in relation to the scheduling of these substances under the Misuse of Drugs Regulations 2001 in due course.

Yours sincerely,

**Dr Owen Bowden-Jones**
**(Chair of ACMD)**

ACMD

Advisory Council on the Misuse of Drugs

# Methylphenidate-related Novel Psychoactive Substances:

# A review of the evidence of use and harms

**March 2017**

## Background

1. In March 2015, a Temporary Class Drug Order (TCDO) was implemented on ethylphenidate following a recommendation from the Advisory Council on the Misuse of Drugs (ACMD) concerning its proliferation in use as a Novel Psychoactive Substance (NPS), particularly in relation to the harms caused by its intravenous administration.

2. Ethylphenidate is an analogue to **methylphenidate** (Ritalin, a licensed medicine), a Central Nervous System (CNS) stimulant which is controlled as a Class B drug. A number of other closely-related substances (3,4-dichloromethylphenidate, methylnaphthidate, isopropylphenidate and propylphenidate) were also included in ACMD's recommendation, to reduce the displacement from ethylphenidate to related substances with similar effects. In June 2015, a further two substances (4-methylmethylphenidate and ethylnaphthidate), which had subsequently appeared on NPS markets, were added to the TCDO.

3. The TCDO on these seven substances was re-laid for a further year, in June 2016. Feedback received by the ACMD from Police Scotland indicated that the TCDO had been effective in reducing the prevalence of these substances and the Council advised that a TCDO level of control was proportionate in the interim, whilst the ACMD gathered further evidence in consideration of permanent control of these substances under the Misuse of Drugs Act 1971.

## Methylphenidate

4. Methylphenidate was developed as a CNS stimulant in the 1960s. It acts primarily as a re-uptake inhibitor for dopamine (DA) and norepinephrine (NE) and has found widespread application in the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Therapeutic effects of DA stimulation are thought to involve a weakening of inappropriate network connections (*i.e.* producing a decrease of "noise"), whereas enhanced NE transmission may function by strengthening appropriate connections (*i.e.* producing an increase of "signal").

5. Methylphenidate formulations include tablets containing 5, 10 or 20 mg of the active ingredient and slow-release tablets containing up to 40 mg.

6. Methylphenidate is listed within the 1971 UN Convention on Psychotropic Substances as a Schedule II material. In the UK, it is controlled as a Class B material and as a Schedule 2 substance under the Misuse of Drugs Regulations 2001 (as amended).

## Methylphenidate-based NPS

7. Reports from Police Scotland cited ethylphenidate as being a public health issue in Edinburgh in 2015. The ACMD recommended a total of seven compounds (including several other analogues of ethylphenidate) be included in the TCDO to prevent users from switching to related drugs with similar harms:
    - **Ethylphenidate** is the simple homologue of methylphenidate. It first appeared as an NPS in the UK in 2011 and became one of the most commonly encountered stimulant NPS.
    - **3,4-Dichloromethylphenidate ('3,4-DCMP')**, the halogenated derivative of methylphenidate appeared in the UK as an NPS in 2013. It is claimed to be several times more potent than the parent compound, with a slower onset of action and longer duration.
    - **Methylnaphthidate ('HDMP-28')**, the naphthyl analogue of methylphenidate, became available in the UK as an NPS in late 2014. In addition to acting as a re-uptake inhibitor for dopamine and norepinephrine, it also acts at the serotonin receptor, and is therefore a triple re-uptake inhibitor, reminiscent of cocaine. It is claimed to have several times the potency of methylphenidate, but with a shorter duration of action.
    - **Isopropylphenidate ('IPP' or 'IPPD')** became available in the UK as an NPS in 2015. In 2013, it had been described in the scientific literature as having a greater effect on dopamine levels than norepinephrine when compared with methylphenidate and as being more resistant to metabolism, resulting in a longer-lasting effect.
    - **Propylphenidate** also began to be advertised in the UK as an NPS in 2015. Little is known of its neurochemical properties, but these can be expected to be similar to isopropylphenidate, being its structural analogue.
    - **4-Methylmethylphenidate**, appeared on online markets following the implementation of the TCDO on the above substances.
    - **Ethylnaphthidate ('HDEP-28'),** the ethyl homologue of methylnaphthidate, also appeared on online markets following the implementation of the TCDO on the above substances.

8. A further five similar substances have subsequently appeared on markets following the TCDO, which have the potential to cause similar harms:
    - ***N*-Benzyl-ethylphenidate** and **3,4-dichloroethylphenidate,** analogues of ethylphenidate**,** have both been seized by the German authorities.
    - **Methylmorphenate**, is the morpholino analogue of methylphenidate.

- **4-Fluoromethylphenidate** and **4-fluoroethylphenidate** are the 4-fluorinated forms of methylphenidate and ethylphenidate, respectively. These are more potent than the non-fluorinated forms.

## Chemistry and Pharmacology

9. Ethylphenidate (Ethyl 2-phenyl-2-(piperidin-2-yl) acetate) is the ethyl homologue of methylphenidate (*see Annex 1*). It is a CNS stimulant and acts as a dopamine reuptake inhibitor and norepinephrine reuptake inhibitor. Low levels of ethylphenidate are known to be formed by transesterification when methylphenidate is used in combination with alcohol (Willard *et al.*; Patrick *et al.*).

10. Reports from users indicate that ethylphenidate is an amphetamine-like stimulant (Police Scotland reports).

11. Willard *et al.*, 2007 also reported that both methylphenidate and ethylphenidate stimulated motor activity in mice, with ethylphenidate having a somewhat smaller effect than methylphenidate.

12. The neurochemical profiles of ethylphenidate, methylphenidate and cocaine are compared in terms of their ability to inhibit dopamine (DA), norepinephrine (NE) and serotonin (5-HT) uptake in Table 1:

| * | Cocaine | ±methylphenidate | ±ethylphenidate |
|---|---|---|---|
| Dopamine uptake $EC_{50}$ (nM) | 250 | 20 | 95 |
| Norepinephrine uptake – $EC_{50}$ (nM) | 392 | 51 | 480 |
| 5-HT uptake – $EC_{50}$ (nM) | 253 | >10,000 | >10,000 |

*Data from, +Willard *et al*., 2007.

**Table 1** Uptake inhibition data for cocaine, methylphenidate and ethylphenidate. $EC_{50}$ = drug concentration for 50% inhibition of uptake (smaller values indicate a higher potency).

13. Ethylphenidate and methylphenidate are both potent inhibitors of dopamine (DA) uptake, and both inhibit norepinephrine (NE) uptake, although ethylphenidate is almost 5 times less potent against NE than DA, while methylphenidate is less selective (Table 1). Both compounds stimulate

motor behaviour in mice, which is consistent with their profiles as psychostimulants.

14. The onset of effects for nasal insufflation is approximately 13 minutes and orally is approximately 23 minutes. The duration of effects is relatively short at two hours.

15. In data recorded from rat brain slices, research was conducted in the nucleus accumbens (NAC) for dopamine efflux and the bed nucleus of the stria terminalis (BNST) for norepinephrine efflux. This data showed that 3,4-CTMP had a bigger effect on dopamine, while ethylphenidate had a relatively modest effect. Both compounds increased norepinephrine levels, which might suggest that they would be vasoconstrictive, leading to hypertension (data provided to ACMD by Professor Colin Davidson - currently at the University of Central Lancashire).

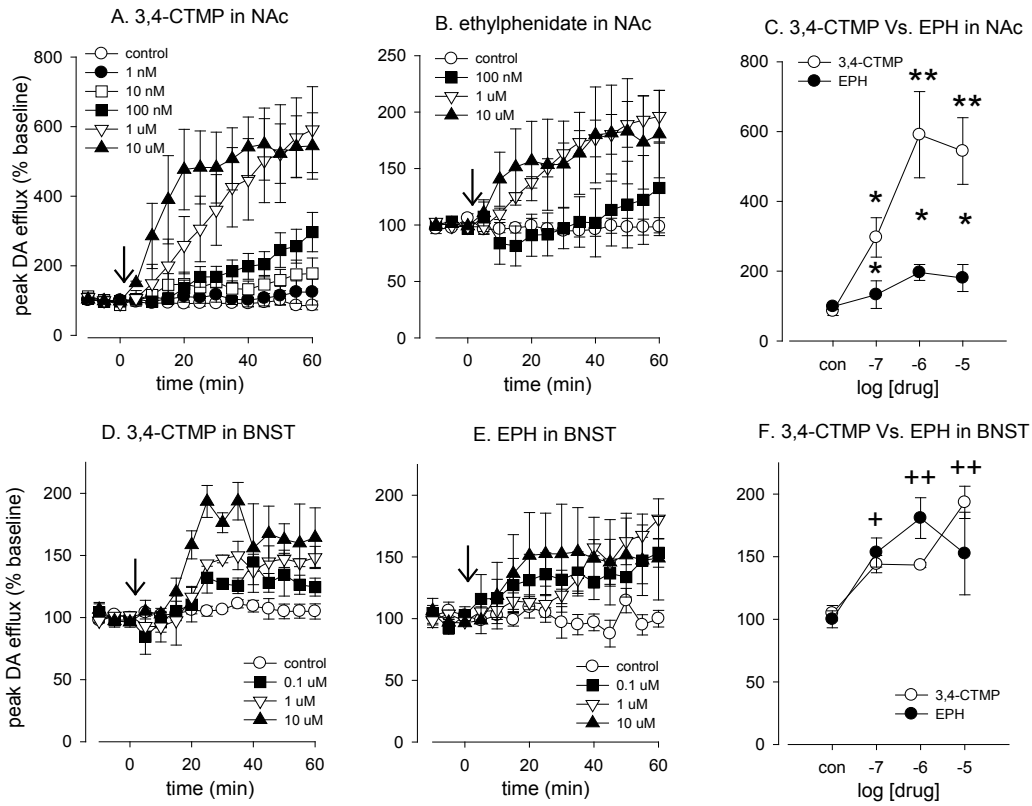



**Figure 1:** Comparison of activity between 3,4-CTMP and ethylphenidate at the NAC for dopamine efflux and the BNST for noradrenaline efflux.

16. A range of closely-related materials have been assessed and found to produce similar effects. A number of these materials have also appeared as New Psychoactive Substances ((Deutsch *et al.* 1996, 2001; Schweri *et al.* 2002; Davies *et al.* 2004; Markowitz *et al.* 2013).

## Prevalence of use

17. Ethylphenidate has been reported to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) by Austria (2016), Greece (2016), the UK (2011, 2013, 2014), Luxembourg (2014), Slovenia (2014), Croatia (2014), Italy (2014), Lithuania (2013), Hungary (2013), France (2013), Denmark (2013), Spain (2013), Finland (2012) and Sweden (2012).

18. Ho *et al*. performed an Internet snapshot survey on the availability, patterns of use and acute effects of ethylphenidate in February 2015. The review concluded that the associated acute harms are stimulant in nature and that ethylphenidate was widely available to users over the Internet.

19. Prior to control, ethylphenidate was widely available on NPS websites and had been routinely identified in Home Office Forensic Early Warning System (FEWS) surveys since 2011. Ethylphenidate was being sold by Internet suppliers and headshops as a replacement for cocaine and marketed both as a single substance 'research chemical' and as a component of 'branded' products such as 'Gogaine', 'Nopaine', 'Fake cocaine', 'Banshee Dust' and 'Evoke'. The single substance was available as a powder, crystals (which commanded a slightly higher price) or 'pellets' (tablets) containing up to 50 mg per tablet.

20. Police Scotland have reported overt injecting practises, needle discards and antisocial behaviour in public places related to the injection of ethylphenidate in Edinburgh. Updates since the implementation of the TCDO report a marked decline in these associated issues.

21. The WHO's Critical Review of ethylphenidate reported that forms of administration include nasal insufflations, oral, anal, vapour inhalation and intravenous injection.

## Polysubstance use

22. Samples taken by WEDINOS have found the following substances in combination with ethylphenidate: methiopropamine, 5-MeO-DALT, phenacetin, 2-aminoindane, phenylethylamine, ephedrine, caffeine, lidocaine, benzocaine and mannitol.

23. Users of ethylphenidate may not be aware that it is often mixed with a variety of other compounds.

## Acute harm

24. As might be expected from a stimulant material which boosts dopamine levels, users report a strong urge to re-dose. One branded formulation, 'Burst', has been reported as causing particular problems in the Edinburgh area, including among injecting drug users, who reported re-injecting repeatedly. There was also a report of an outbreak of *Staphylococcus aureus* and *Streptococcus pyogenes* infections in this area associated with NPS injecting, which was believed to involve ethylphenidate. Information from Police Scotland (March 2016) was that *Staphylococcus* and *Streptococcus aureus* bacterial infections were declared over in October 2015, following the TCDO.

25. Public Health England's report (Shooting up Infections among people who injected drugs in the UK, 2015, updated November 2016) described a large outbreak of soft tissue infections among people who injected psychoactive drugs in the Lothian NHS Board area of Scotland. Ethylphenidate was cited as an example of a common recently emerged psychoactive drug associated with short "rushes" and frequent injecting episodes.

26. The majority of NPS-related presentations to Accident and Emergency in Edinburgh had been associated with use of 'Burst' (March to September 2014). The use of ethylphenidate-based products was associated with bizarre and violent behaviour in Edinburgh. Following the introduction of the TCDO the number of presentations at Edinburgh Royal Infirmary related to ethylphenidate injecting had reportedly reduced from 27 in April 2015 to 3 for the same month the following year.

27. Police Scotland reported that related practices included: communal injecting, users injecting each other due to rapid onset of effects and loss of fine motor control, needle sharing, injecting in unsanitary environments, high-risk injecting (in the neck and groin), and preparation with citric acid to improve water solubility, which additionally increases the corrosive nature of the substance *in vivo*.

28. These practices were thought likely to lead to a high risk of bacterial infection and local tissue damage. The injected contents were sometimes not fully solubilised and users were injecting without filtering. Police Scotland have seen reports of the solution partially solidifying on injection. Intravenous drug users in Edinburgh and Lothian were experiencing injuries related to injecting as a consequence of injecting with ethylphenidate.

29. Avon and Somerset and Devon and Cornwall Police have heard similar reports. Throughout 2014 the market town of Taunton in Somerset had

been hit with an epidemic of NPS injecting with all products originating from the one headshop located on the main High Street. The injecting was happening in open public places including public toilets and users were abandoning their injecting materials on the surrounding ground resulting in one occasion with a local 6-year old receiving a needlestick injury. In one clear up day in Taunton town centre, over 200 needles were recovered. The injecting and resulting anti-social behaviour reached such a point that the communities set up their own Action Group (SWAG) and worked with the Police and Council to reduce the harms being caused. In December 2014 the Police applied for and achieved the closure of the headshop under anti-social behaviour legislation. The products most commonly injected were Gogaine, Posh and Ching, all of which are ethylphenidate-based.

30. The National Programme of Substance Abuse Deaths (NPSAD) reported that up to February 2017, ethylphenidate had been found in 28 cases of post mortem toxicology. There have been 17 cases where ethylphenidate was implicated in the cause of death. In the majority of these cases other drugs including NPS were present.

31. Data provided to the University of Hertfordshire by the National Records of Scotland as part of the EU-MADNESS project indicated that there were five deaths in 2014 and one death in 2015 where ethylphenidate was implicated in the cause of death. In addition, a death involving 4F-ETH (4'-fluoro-ethylphenidate) occurred in July 2016 (unpublished data up to September 2016). As with the NPSAD cases, other NPS were often implicated, along with opiates/opioids such as morphine and methadone.

| **Month & Year of death** | **Gender** | **Age at death** | **Nature of death** | **Cause of death** | **Substances also present in Post mortem** |
|---|---|---|---|---|---|
| January 2014 | Male | 20 | Accidental poisoning | Ethylphenidate, methoxphenidine, morphine, pyrazolam and etizolam intoxication, on-going drug abuse | Fluoxetine, pregabablin, zuclopenthixol, alcohol |
| May 2014 | Male | 38 | Accidental poisoning | $\alpha$-methyltryptamine and ethylphenidate intoxication, on-going drug abuse | Diphenhydramine, etizolam |
| June 2014 | Female | 31 | Accidental poisoning | Bronchopneumonia, chronic drug abuse, methadone and ethylphenidate intoxication | |
| October 2014 | Female | 46 | Drug dependence | Disseminated *Streptococcus pyogenes* (Group a), drug abuse (heroin and ethylphenidate) | Morphine, codeine, fluoxetine, paracetamol, mirtazapine, diazepam |
| October | Male | 45 | Accidental | Intracerebellar haematoma, | Morphine, |

| | | | | | |
|---|---|---|---|---|---|
| 2014 | | | poisoning | ethylphenidate toxicity, drug abuse | codeine, paracetamol |
| March 2015 | Male | 37 | Accidental poisoning | Adverse effects of heroin, methadone, and ethylphenidate, atherosclerotic coronary artery disease, drug abuse | Lamotrigine, carbamazepine |
| July 2016 | Male | 24 | Accidental poisoning | Complications of MDMA/MDA and 4F-ETH toxicity, | Lignocaine, alcohol |

**Table 2**: Deaths involving ethylphenidate and analogues, Scotland Uptake

32. During the period 1st January 2015 to 13th March 2015 the National Poisons Information Service (NPIS) reported there were 609 accesses to the TOXBASE entry for ethylphenidate, 506 during 2014 and 103 during 2015 (to 13th March).

33. During the period 1st January 2011 to 17th March 2015 (inclusive), NPIS also reported 106 cases discussed with NPIS, where there had been exposure to ethylphenidate or a product previously shown to contain ethylphenidate as a major ingredient. Of these, 71 involved exposure to a single product and 35 involved reported use of other substances in addition. The most prominent clinical features reported during telephone enquiries related to:
    - Tachycardia or palpitations
    - Agitation or anxiety
    - Hallucination
    - Reduced level of consciousness.

34. The progress report of the UK Early Warning System (EWS) to the EMCDDA (*January to June 2014*) reported the detection of ethylphenidate.

35. There had been three reports of ethylphenidate acute toxicity which required hospitalisation. The effects were similar to those of other stimulants, including tachycardia, hypertension, palpitations, dilated pupils, anxiety, fever, agitation, paranoia and tremor (Bailey, *et al.*).

36. There is one published case report of analytically confirmed acute ethylphenidate toxicity. This was a 26-year-old male who presented with anxiety, paranoia, visual disturbance, and chest pain following use of 500 mg ethylphenidate. On presentation to the Emergency Department, he was restless, tachycardic and hypertensive.

37. Parks *et al*. reported that there were 19 cases where ethylphenidate was positively identified during a search of post-mortem toxicological analysis in

the period July 2013 to December 2014. In five of these cases, ethylphenidate was specifically mentioned in the cause of death.

## Chronic harm

38. There is currently no data available on the potential for chronic harm associated with ethylphenidate or related analogues. However, with this frequent pattern of injecting, it is likely to lead to an increased risk of hepatitis C or HIV.

## Social Harms

39. Prior to the implementation of the TCDO, the use of ethylphenidate-based products was associated with antisocial behaviour in the vicinity of headshops. There were also reports from Police Scotland on increased public injecting and publically discarded injecting paraphernalia during the peak of the ethylphenidate epidemic.

40. NHS Lothian Incident Management Team (IMT) dealt with a large outbreak of localised and invasive infections in people who inject drugs in the Edinburgh area between October 2014 and October 2015. This was attributed to ethylphenidate injecting in nearly all cases. Chaotic behaviour and the frequency of injecting associated with this contributed to the spread of infection in the population.

41. The IMT reported that poor treatment compliance and late presentations by users made the situation difficult to manage. The introduction of the TCDO led to a reduction in availability of ethylphenidate and appears to have contributed significantly to a fall in case numbers.

## International data

42. Ethylphenidate is controlled in China, Denmark, Estonia, Germany, Hungary, Italy, Poland, Portugal, Slovenia, Sweden and Turkey. It is also classified under analogue scheduling in the US and Australia.

43. At the 38th Expert Committee on Drug Dependence in November 2016, ethylphenidate was recommended to be controlled under Schedule 2 of the United Nations Single Convention on Narcotic Drugs 1971.

## Legitimate use

44. The ACMD are currently carrying out a consultation with stakeholders within government, industry and academia with regards to the legitimate uses of these substances and will provide further advice in relation to scheduling of

these compounds under the Misuse of Drugs Regulations 2001 at a later date.

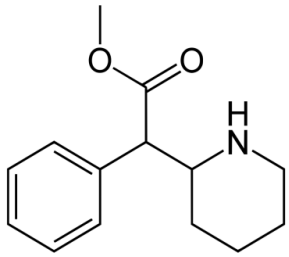
## Recommendation

45. The ACMD recommends that **ethylphenidate** and the following closely-related materials be controlled under the Misuse of Drugs Act 1971 as Class B based on their actual or potential harms:

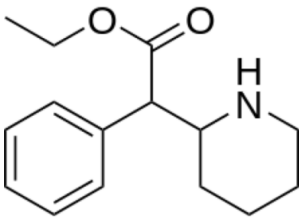
**Methylnaphthidate ('HDMP-28')**
**Isopropylphenidate ('IPP' or 'IPPD')**
**Propylphenidate**
**4-Methylmethylphenidate**
**Ethylnaphthidate ('HDEP-28')**
***N*-Benzyl-ethylphenidate**
**3,4-Dichloroethylphenidate**
**3,4-Dichloromethylphenidate ('3,4-DCMP')**
**Methylmorphenate**
**4-Fluoromethylphenidate**
**4-Fluoroethylphenidate**

46. These substances should be inserted into Schedule 2, Part 2, Paragraph 1 (a), of the Misuse of Drugs Act 1971 (as amended).

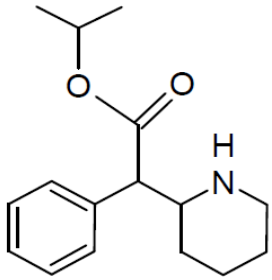
*Annex 1: Chemical Structures of some of the substances*



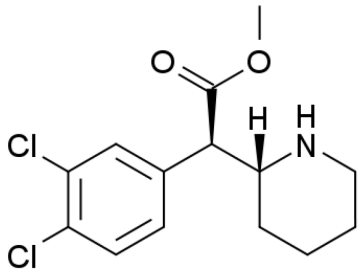
**Methylphenidate (Ritalin)**



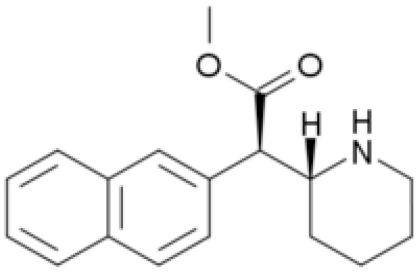
**Ethylphenidate**



**Isopropylphenidate**



**3,4-Dichloromethylphenidate**



**Methylnaphthidate ('HDMP-28')**

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