ACMD

Advisory Council on the Misuse of Drugs

ACMD Standard Operating Procedure (SOP) for using evidence to make classification, scheduling and other recommendations

V.2.0	**December 2024** - Inclusion of Classification chapter (Secretariat: Alasdair Forrest / Lydia Chaloner)

Intended purpose of this Standard Operating Procedure

This Standard Operating Procedure (SOP) is a central document developed by the Advisory Council on the Misuse of Drugs (ACMD) to allow the Council to follow a consistent mechanism to prepare evidence-based advice. This document describes the processes followed by the ACMD in a consistent and transparent manner which lead to the formulation of recommendations.

The ACMD may undertake reviews on substances either in response to a government commission or as self-commissioned work, which is reflected in a Project Initiation Document (PID) when initiating a project (Chapter 1).

The ACMD follows a standard process for collecting, analysing and presenting evidence (Chapter 2).

ACMD recommendations are guided by an assessment of health and social harms, based on the evidence available at the time of the review (Chapter 3). A decision on classification (Chapter 4) relies on a range of factors, including evidence of actual and potential harms, alongside comparisons to the harms of other controlled substances.

The ACMD makes scheduling recommendations under the Misuse of Drugs Regulations 2001 (as amended) (Chapter 5) for all drugs controlled under the Misuse of Drugs Act 1971.

Role of the ACMD

The role of the ACMD is described in the Misuse of Drugs Act 1971:

“It shall be the duty of the Advisory Council to keep under review the situation in the United Kingdom with respect to drugs which are being or appear to them likely to be misused and of which the misuse is having or appears to them capable of having harmful effects sufficient to constitute a social problem.”

Chapter 1: Identifying and approving a report theme

Proposals for new ACMD projects follow a consistent mechanism of being considered and approved centrally by the ACMD Full Council before being taken forward by an ACMD Standing Committee or Working Group. This ensures that all projects are governed by the ACMD Full Council and allows ACMD members to contribute to the scope of the proposed areas of work.

Process for approving the initiation of a new report

A Project Initiation Document (PID) will be presented to the ACMD's Full Council for consideration. The ACMD Full Council will then collectively decide on whether to approve the project. A proposal for a new project can be submitted to the ACMD Full Council for consideration via the ACMD's Secretariat at any time. ACMD members also have the opportunity to present and discuss potential proposals at ACMD Away Days.

Structure of an ACMD project initiation document (PID)

Proposals should include:

1. **Project title**
2. **How the project was commissioned**. Whether the advice has been commissioned by Government or self-commissioned by the ACMD's membership.
3. **Topic background & key issues**
4. **Overview of the quality of available evidence in the area**. Projects are unlikely to be approved if there is insufficient evidence upon which to draw recommendations.
5. **Project aim.** The scope of the report needs to be described with clear and defined questions, and an explanation of what is and is not covered within the report.
6. **Membership**. A consideration of membership, Chair and possible co-option
7. **Proposed timescale for completion**
8. **Further work**. Whether the proposal would be likely to require the commissioning of further work (if this is possible to foresee). Whereas the ACMD does not normally undertake original research, where this is undertaken this would be conducted within Home Office guidance on research governance. This will help with the allocation of resources.

Chair of proposed committee/working group

The Chair of the chosen project is usually the ACMD member who proposed the subject area. However, this is not always the case and members who have proposals but who are unable to Chair the group should not be discouraged from submitting a proposal. Any member could express interest to chair a working group.

Chapter 2: Collecting, analysing and presenting evidence

The ACMD uses evidence from a wide range of sources to develop its recommendations. Examples include peer-reviewed research, published reports and expert opinion (Table 1). Assessing the quality and relevance of different types of evidence is a critical part of the ACMD's work.

Collecting evidence to answer the identified questions

For each question listed on the PID, the Working Group should:

i. search appropriate databases using specific keywords to help answer the question(s).
ii. identify organisations/individual experts who should be approached.

Table 1: Sources of data

Sources of data	Examples of types of data
Published research literature	Peer reviewed journals
Conference papers/abstracts	Unpublished/not peer reviewed papers
Evidence from Government departments and Devolved Nations	Crime Survey for England and Wales
Evidence from other UK organisations	Drug poisoning deaths and mortality data
Evidence from non-UK organisations	Prevalence data from other countries
Expert and/or stakeholder opinions	
Other sources	Media, user fora

Analysing evidence

Once evidence has been collected a bespoke analysis will be agreed by the Working Group. The chosen method of analysis will depend on the purpose of the report and the identified questions. The Working Group may choose to finalise the specific methodology once it is clearer what evidence is available.

The Chair of the Working Group will be responsible for deciding the methodologies used.

Presenting recommendations

Each ACMD report should include specific and targeted recommendations, including:

a) Who the recommendation is intended for;

b) A measure of implementation (i.e. likely indicators to show that the recommendation has been carried out);
c) Metrics for assessing the intended effect (i.e. how one could measure the intended (or unintended) effect of the recommendation).
d) Identified gaps in evidence (or where there is weak or contradictory evidence) should be highlighted and where appropriate, a recommendation for further research made.

Presenting the quality of evidence in reports

Each ACMD report should include an annex describing the methods used in data collection and analysis and the quality of evidence supporting individual recommendations, where possible.
For example, a report's annex may include:

a) Range of evidence sources;
b) Quality of evidence (design, limitations, bias);
c) Applicability to report questions;
d) Determination of causality (using for example the Bradford Hill criteria).

Quality assurance for ACMD reports

The ACMD's secretariat will be responsible for undertaking a quality assurance step prior to final draft advice being presented to ACMD Full Council for approval. At this stage of the approval process, the Secretariat will detail the quality assurance process followed for the report to the ACMD Chair and the respective committee/working group chair(s).

Checklist for ACMD projects

a) Has the scope of the workstream been identified?
b) Has the Working Group followed the PID, including addressing the questions listed?
c) Has the presented evidence answered the identified questions?
d) Does the report include in the annex:
    - a description of the methods used in data collection, search criteria and analysis?
    - the organisations and experts approached?
e) Has the methodology for analysing the evidence changed as a result of the evidence?
f) Does the report clearly state the sources and types of data?
g) Does the report indicate the quality of evidence? If possible, is the quality of individual recommendations discussed?

Chapter 3: Consideration of health and social harms

The ACMD follows a health and social matrix when developing recommendations. All ACMD reports that assess the overall harms of a drug should use the health harms matrix (Table 2) and social harms matrix (Table 3) to identify and consider potential harms across a range of domains to inform that assessment. The matrices are not intended to be prescriptive but instead provide a relatively simple mechanism to ensure that substance-related health and social harms are fully considered.

Definitions

For the purposes of ACMD's work:

Health harms can be defined as "a negative effect on health resulting from drug use, whether direct or indirect".

Health harms are classified by health professionals using a range of different approaches. These metrics include type of harm (physical versus psychiatric), time of occurrence (acute versus chronic), body system involved (e.g. cardiovascular, respiratory) and disease process (e.g. infection, trauma).

Social harms can be defined as "damages to human welfare, security and autonomy that occur in the relations between individuals, communities and institutions of society".

Social harms may emerge as a direct consequence of drug use or indirectly from drug use or through policy and enforcement responses to drug use. Many of these harms are predictable, but others may be unexpected and/or unintended. There are multiple bearers of social harms. These should be identified in reports and are broadly categorised as:

i. The individual who uses drugs;
ii. Others affected by drug use, such as family and peers;
iii. Communities and social structures.

Part of the complexity of describing drug-related harm is that it can occur across multiple systems and with poorly understood underlying mechanisms. Many drugs will cause harms across several harm domains.

Drug-related harm may also be experienced by those who are not using drugs themselves. Relatives, friends, the wider community and the environment are examples. These have been described in the matrices under the section 'harm to others'.

Methodology and development of the matrices

Two working groups of the ACMD developed the matrices for health harms and social harms, having considered the methodologies utilised for assessing both.

The methodology for assessing health harms reviewed existing work already carried out in this area, existing models and frameworks, including classifications used by the National Institute for Health and Care Excellence (NICE), the Medicines and Healthcare products Regulatory Agency (MHRA), Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM 5 (APA, 2013)) and International Statistical Classification of Diseases and Related Health Problems (ICD 10/11 (WHO,1992; WHO, 2018)). None were suitable for the needs of the ACMD and were not able to encompass the range of harms a drug could cause to an individual or others.

The ACMD also considered other ways which drug harms have been considered such as the "multi criteria decision analysis model" (Nutt, 2010) but again this set out to compare drug harms and rank harm which is not the goal of the ACMD's work. The ACMD did not find any evidence that the use of quantification or scoring in a harms assessment was likely to be more meaningful than structured descriptions. The use of quantification of harm metrics is not indicated for the ACMD's work.

The methodology for assessing social harms has been adapted from the work of Greenfield and Paoli (2013) on the assessment of the harms of crime, and the EMCDDA (2020) operating guidelines on the risk assessment of new psychoactive substances.

The patterns of drug use and characteristics of the person using the drug

It is useful to consider factors related to the drug's properties, patterns of use and characteristics of the drug users.

Patterns of use

- Dose
- Potency
- Purity and risks of adulteration
- Potential for dependence
- Potential interactions with other drugs/alcohol
- Routes of administration
- Frequency of use
- Length of use.

Characteristics of the person using the drug

- Age
- Sex
- Physical health (e.g. liver and renal function, underlying heart or lung disease)
- Psychiatric/psychological health (e.g. depressive episode)
- Social health (e.g. disrupted social networks)

- Genetic factors (e.g. vulnerability to drug dependence)

Presenting conclusions

Through structured discussion by an ACMD sub-committee or working group, taking into account the domains and the bearers of the main harms identified, consensus on overall harm should be reached.

Associated recommendations should be justified by indicating, where appropriate, how the recommended action is considered to reduce the identified harms including suggested metrics to measure success. Similarly, where the report has shown that there is a risk of indirectly increasing harm through recommendations, ameliorating actions should also be identified.

Conclusions and recommendations are ratified by the ACMD Full council prior to publication.

Table 2: Health harms matrix

Harm domain	Harm example	Data source example
Harms to user		
1. Physical health harms		
1.1. Mortality	acute overdose, misadventure, drug-impaired fatal road crashes	Mortality statistics (ONS NRS, NISRA, NPSUM) Coroners' reports Confidential enquiries Fatal accident inquiries
1.2. Neurological	drug-induced coma, seizures	Case reports Case series studies Service user feedback Treatment trials Clinician feedback HES data MHRA Yellow Card scheme (for licensed medicines) NPIS data Congenital anomaly registries UK Teratology Information Service
1.3. Cardiovascular	acute cardiac arrhythmias or MI, venous thrombosis from injections, health harms associated with injecting crushed tablets	
1.4. Respiratory	respiratory depression, lung disease associated with smoking drugs	
1.5. Hepatic/ gastroenterological	drug-induced hepatitis, drug-induced vomiting, constipation	
1.6. Genitourinary/ renal	ulcerative cystitis, nephropathy, drug-induced glomerulosclerosis	
1.7. Blood/ nutrition/ endocrine	clotting abnormalities, drug-induced disseminated intravascular coagulation, drug-induced SIADH, indirect nutritional deficiencies	
1.8. Reproductive	early labour, adverse foetal effects of drug use, testicular atrophy	
1.9. Musculoskeletal	drug-induced rhabdomyolysis	
1.10. Immunological	immunosuppression	

1.11. Ear, Nose & Throat (ENT)	septal damage from drug snorting	
1.12. Dermatological / dental	skin abscess and necrosis secondary to injecting, oral cancer, dental decay from long-term drug use	
1.13. Multiple	issues related to repeated non-lethal overdoses, health harms related due to routes of administration covering direct and indirect effects (e.g. blood-borne virus)	
2. Mental health harms		
2.1. Intoxication		Case reports Case series studies Service user feedback Treatment trials Clinician feedback HES data MHRA Yellow Card scheme (for licensed medicine) NPIS data
2.2. Delirium	acute confusional states	
2.3. Psychosis	individuals with pre-existing mental health conditions, such as schizophrenia or bipolar disorder, may be more prone to violent behaviour if drug use triggers psychosis. drug induced psychosis, persecutory thinking	
2.4. Mood disorders	including suicide risk	
2.5. Memory disorder	dementia and other memory deficits, short term memory loss, cognitive impairment	
2.6. Anxiety		
2.7. Psychological dependence and addiction	including tolerance, withdrawal symptoms and craving	
Harms to others		
3. Physical health harms		
3.1. Infective process	blood borne virus (BBV) transmission	Surveys of BBV Office for Health Improvement and

		Disparities (OHID) and Devolved Nations
3.2. Other physical harms to others	road traffic accidents whilst intoxicated, violence whilst intoxicated	Department for Transport

Table 3: Social harms matrix

Harm domain	Notes and examples	Notes on data sources
Harms to user		
4. Loss of tangibles		
4.1. Education	including exclusion from education, educational disengagement, and under achievement (qualifications)	Drug and alcohol related permanent and fixed period pupil exclusions (DfE; Devolved Nations)
4.2. Employment	including loss of employment; lack of and under-employment; loss of income and low wages; and tangible losses through workplace discrimination (identification as a person who uses drugs)	UK labour market data does not include reason for loss of employment. Organisations such as the Health and Safety Executive, Unions, employers' associations and sector bodies occasionally publish the findings of surveys and enquiries into substance use in the workplace
4.3. Housing	loss of accommodation as a direct or indirect consequence of drug use, including loss of employment, imprisonment or break down in relationships	Ministry of Housing, Communities and Local Government homelessness statistics; OHID drug treatment (and equivalent bodies in Devolved Nations) includes data on housing status; homelessness and housing charities/third sector organisations, and housing associations periodically commission research into this topic.
4.4. Crime	direct harms may include loss of autonomy and liberty as a result of sanctions (e.g. imprisonment,	Ministry of Justice (and equivalent bodies in Devolved Nations) datasets on arrests for recorded crime, prison

	supervision orders, licence conditions), whilst indirect harms may include loss of other tangibles (e.g. employment, housing, travel) as a result of disclosure of penalties (e.g. imprisonment, police/court caution). There may also be secondary escalation of criminality (and drug use) through involvement in the criminal justice system. This category also includes harms related to being a victim of drug-related crime. Involvement in criminal gang groups, money laundering, strategies to prevent prosecution.	population; local analyses of orders including Drug Testing and Treatment Orders (DTTO), Drug Rehabilitation Requirements (DRR); bespoke analyses of NDTMS; nature of crime Module from the CSEW ('the victim believed the perpetrator(s) to be under the influence of drugs')
5. Loss of relationships		
5.1. Personal relationships	loss of relationships with children and other family members, friends and social support networks and the wider community. As positive social relationships are considered important forms of social capital and a component of recovery capital, loss of these may compound drug-related harm. Similarly, a narrowing of social relationships and social identity around drug-use may promote harm.	DFE statistics on the characteristics of children in need.
6. Other harms to the user		
6.1. Sexual exploitation and violence	including exploitative sex work to pay for	HO Annual report on modern slavery; OHID

	drugs, sexual violence, and human trafficking. Children and young people may be provided with drugs as part of sexual exploitation practices by adults, involvement in 'county lines'	young people treatment data on service users reporting experiencing sexual exploitation; Sexual violence and grooming data (MoJ recorded crime data) does not include breakdown by offences related to substance use; NSPCC annual reports on child safety may include exploitation themes; Barnardo's reports.
6.2. Stigmatisation	stigmatisation may lead to prejudice and discriminatory practice and behaviour towards both people who use drugs and associated groups (e.g. siblings, children of people who use drugs). This can lead to negative (self) labelling, prejudice, exclusion, and discrimination, which may undermine the provision, access, and the quality of support, and which serves to reproduce and reinforce broader health and social inequity.	Scottish Government public attitudes towards people with drug dependence and people in recovery research 2016. Stigma frameworks (Stangl et al, 2019) can assist in identifying relevant domains for analysis; Social Media review/ survey.
Harms to others		
7. Injury		
7.1. Violence (general)	including psychopharmacological, economic-compulsive, and systemic violence	Nature of crime Module from the CSEW ('the victim believed the perpetrator(s) to be under the influence of drugs'); Offending, Crime and Justice Survey
7.2. Intimate partner violence	including harm resulting from aggression, sexual coercion,	Intimate violence Module from the CSEW - victims of partner abuse in the last year are asked

	psychological abuse and controlling behaviours	whether they thought the offender (or offenders) was under the influence of alcohol or illicit drugs at the time of the incident. In addition, they are asked whether they (the victim) were under the influence of alcohol or illicit drugs at the time of the incident.
8. Accidents		
8.1. Traffic 8.2. Industrial 8.3. Personal	including harms related to fatal and non-fatal accidents, property damage, loss of earnings, social costs of injury direct costs (e.g. emergency and health services, courts, traffic delay expenses)	Ministry of Justice (and equivalent bodies in Devolved Nations) datasets on arrests for recorded crime; Department for Transport Reported Road Casualties Great Britain self-reported drug driving tables; British Social Attitudes Survey; NatCen Omnibus Survey Driver behaviour Module; DVLA data on number of individuals who have been disqualified from driving after a drug-driving offence; Health and Safety Executive (HSE)
9. Other harms		
9.1. Foetal harm	long term social harms to children resulting from pre-natal effects of drugs, poor maternal health and wellbeing during pregnancy, or harmful environments during pregnancy. These are distinct from developmental harms	
9.2. Developmental	including family adversity, economic and emotional wellbeing, and harms	Local routine ACE enquiry data; National ACE Survey Public Health Wales

		resulting from adverse childhood experiences (ACEs) directly and indirectly related to parental/family drug use. Indirect adverse childhood experiences include physical abuse; sexual abuse; emotional abuse; physical neglect; emotional neglect; witnessing intimate partner violence; household mental illness; parental separation or divorce; imprisoned household member. ACEs may cluster and they have been associated with substance use, and behavioural and social problems later in life (including economic costs)	
9.3.	Crime against others	social harms to victim of crime; loss of economic support for family members; increase in acquisitive crime, growth in serious and organised crime, fear of crime leading to a loss in confidence in formal criminal justice structures; fraud and money laundering; corruptions of public official and public office	Ministry of Justice (and equivalent bodies in Devolved Nations) datasets on arrests for recorded crime; Nature of crime Module from the CSEW ('the victim believed the perpetrator(s) to be under the influence of drugs'); Offending, Crime and Justice Survey
9.4.	Environmental damage	harms resulting from the production of drugs including environmental contamination, deforestation, land (re)appropriation, and unsustainable	

		agricultural and production practices	
9.5.	Economic costs to society	including costs from reduced productivity, loss of productive life years; healthcare; police; prisons; probation; courts; crown prosecution service; implementation of legislation; social services; customs; insurance; societal and personal costs of victims of crime	Academic papers; Government reports
9.6.	Community costs	harms resulting from the impact of drug use, drug markets, and legislative responses on social cohesion, community reputation, perceptions of community safety, and stigmatisation	Local authority Land and Environmental Services routinely collect data on call out responses for needle pickups. These trends give a useful proxy measure of public nuisance associated with drug related litter. National and local trading Standards.
9.7.	Global harms	harms that are borne by producer and transit countries because of drug use in consumer countries and global legislative responses. These include all of the harms described in other categories, destabilisation of government, economies and infrastructure; violent conflict; exploitation and people trafficking. These are harms that may disrupt achievement of the goals of the UN's 2030 Agenda for Sustainable Development	Sustainable Development Goal Indicators (ONS; 2030 Agenda for Sustainable Development) Information from the World Health Organization and UNODC.

Chapter 4: Making Classification Decisions

The ACMD follows a standard process to consider the appropriate mechanisms to control substances under drug legislation in the UK. In the UK, there are two pieces of legislation which are relevant to the use of drugs:

i. The Psychoactive Substances Act 2016 (PSA)
ii. The Misuse of Drugs Act 1971 (MDA)

Further detail regarding the Psychoactive Substances Act 2016 and the Misuse of Drugs Act 1971 can be found in *Table 4, Table 5,* and *Figure 1* below.

Psychoactive Substances Act 2016

A substance is subject to the Psychoactive Substances Act 2016 when it is defined as capable of producing a psychoactive effect when consumed by a person,

The following are explicitly exempted:

- Controlled drugs
- Medicinal products
- Alcohol
- Nicotine
- Tobacco products
- Caffeine or caffeine products
- Food (and does not include a prohibited ingredient)

Under the PSA it is an offence to produce, supply, offer to supply, possess with intent to supply, import, or export substances with the intention to consume the substance for its psychoactive effects. There is no possession offence except in custodial settings.

Misuse of Drugs Act 1971

The Misuse of Drugs Act 1971 controls dangerous or otherwise harmful substances in one of three Classes: A, B and C. Under the MDA drugs can be controlled either by:
i) name, or;
ii) a description of their chemical structure (commonly referred to as a ‘generic definition’), which provides control of multiple related substances.

The Misuse of Drugs Act 1971 makes it an offence to produce, supply, offer to supply, possess with intent to supply, import, or export a controlled drug. There is a possession offence in the Misuse of Drugs Act 1971 for both personal possession and in custodial settings.

The severity of offences within the Misuse of Drugs Act 1971 are greater than the Psychoactive Substances Act 2016 and increase from Class C to Class B and then to Class A.

The ACMD's role is advisory and hence the Government is not obliged to follow ACMD advice. The final decision on legislative change is for Government to make and this may consider a wider range of factors beyond the ACMD's remit.

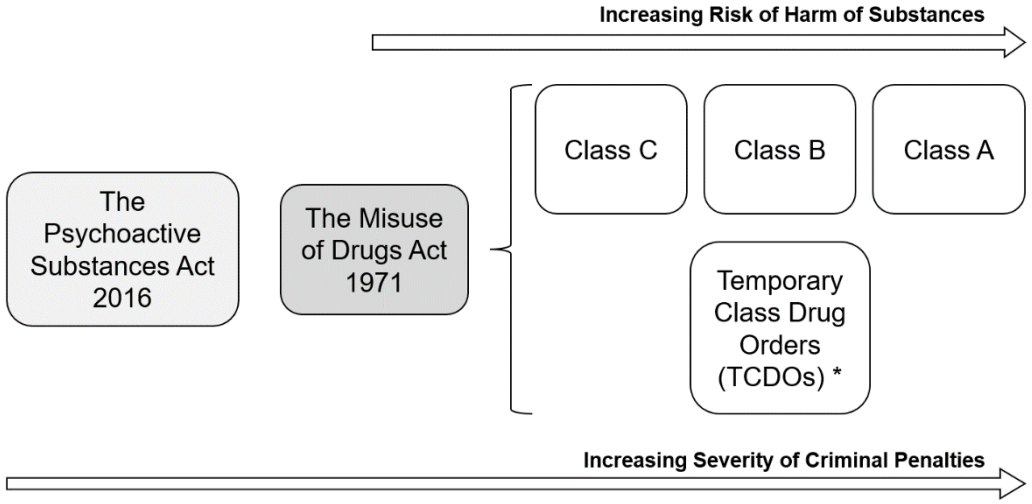

Figure 1: Diagram highlighting the different UK drug legislation for the control of substances, showing the increasing severity of criminal penalties and risk of harm of controlled substances. The arrow indicating 'risk of harm' is the ACMD's own assessment and does not extend towards the PSA 2016, which does not consider the harms associated with a substance, only its psychoactive qualities. In addition, the ACMD's disposition suggests that increasing substance class is linked with increasing risk of harm. * Possession of a temporary class drug is not an offence in a custodial setting under a TCDO.

ACMD's guiding principles of classes within the Misuse of Drugs Act 1971

For substances that require control following a harms assessment:

Class A: Recommendations for Class A are typically for those substances which have the greatest risk of harm to the user and/or wider society. Class A substances have the highest associated penalties under the Misuse of Drugs Act 1971, as outlined in *Table 5* below.

Class B: Recommendations for Class B are typically for those substances that have a lower associated risk of harm to the user and/or wider society than substances in Class A. Class B substances have lower associated penalties than Class A under the Misuse of Drugs Act 1971.

Class C: Recommendations for Class C are typically for those substances that have the lowest associated risk of harm to the user and/or wider society than substances classified under Class A or Class B. Class C substances have lower associated penalties under the Misuse of Drugs Act 1971 than Class B or A.

Temporary Class Drug Orders (TCDOs)

Temporary Class Drug Orders (TCDOs) were added to the Misuse of Drugs Act 1971 in 2011 and were designed to enable rapid action on emerging novel psychoactive substances (NPS), where a time delay may result in a risk to health. TCDOs allow for new, uncontrolled psychoactive substances to be placed under immediate temporary control, if deemed necessary. Before the enactment of the Psychoactive Substances Act 2016, substances which fell outside the scope of the Misuse of Drugs Act 1971 were uncontrolled.

This level of control may be considered if it appears that the substance has the potential for causing harm. The ACMD have made TCDO recommendations in the past (examples include benzofuran compounds and NBOMe substances).

TCDOs come into rapid effect and last for up to 12 months, on the understanding that this is a sufficient period for evidence relating to harms to be gathered and assessed, in order for a decision to be made regarding permanent control. Therefore, TCDOs lapse after 12 months, or sooner if they become a controlled substance within Class A, B, or C under the MDA. It is possible to relay an order if a lack of evidence on harms remains and further time is warranted to decide permanent control. To date, substances subjected to TCDOs have resulted in permanent control under the Misuse of Drugs Act 1971; no substance has moved from temporary control to uncontrolled status or control under the PSA.

A framework of criminal penalties similar to those under the 3-tier classification applies to substances that are subject to temporary control. TCDOs have penalties commensurate with Class B substances, as stated in the MDA 1971, including a higher level of penalty that the PSA, excepting no offence for possession, as detailed in *Table 5*.

The key benefits of a TCDO are:

i. *Rapid mechanism to strict controls*; a TCDO can come into effect from as little as 12 days, following completion of advice (e.g., benzofuran compounds and NBOMe substances).
ii. *Legal powers*: a TCDO equips law enforcement officers and the criminal justice system with powers under the MDA to take appropriate action against offenders, which are not offered by the PSA.

Table 4: Various legislative frameworks available in the UK and their applicability for substance control.

Legislative Framework	Applicability
PSA	Drugs (hence psychoactive substances) are caught under the PSA owing to their ability to produce a psychoactive effect and not their harms.
TCDO	Where there is insufficient evidence at that time and the time to undertake a full harms assessment is considered too great given the potential risk of leaving in PSA only.
MDA	Where there is evidence of significant health and social harms available, requiring permanent legal control to safeguard the public.

Table 5: Penalties for offences under the Psychoactive Substances Act 2016, TCDOs and the Misuse of Drugs Act 1971. There are additional factors involved when determining the seriousness of an offence and the length of any sentence. The Sentencing Guidelines ensure that judges take a consistent approach to sentencing and appropriately considers further factual elements, which may act as aggravating and mitigating factors.

Offence	Psychoactive Substances Act 2016	Misuse Of Drugs Act 1971			
		TCDOs	Class C	Class B	Class A
Possession	None	None	Up to 2 years in prison, an unlimited fine, or both	Up to 5 years in prison, an unlimited fine, or both	Up to 7 years in prison, an unlimited fine, or both
Possession in a custodial institution	Up to 2 years in prison, an unlimited fine, or both	None	Up to 2 years in prison, an unlimited fine, or both	Up to 5 years in prison, an unlimited fine, or both	Up to 7 years in prison, an unlimited fine, or both
Possession with intent to supply	Up to 7 years in prison, an unlimited fine, or both	Up to 14 years in prison, an unlimited fine, or both on indictment; and 6 months' imprisonment and a £5,000 fine on summary conviction	Up to 14 years in prison, an unlimited fine, or both	Up to 14 years in prison, an unlimited fine, or both	Up to life in prison, an unlimited fine, or both
Production	Up to 7 years in prison, an unlimited fine, or both	Up to 14 years in prison, an unlimited fine, or both on indictment; and 6 months' imprisonment and a £5,000 fine on summary conviction	Up to 14 years in prison, an unlimited fine, or both	Up to 14 years in prison, an unlimited fine, or both	Up to life in prison, an unlimited fine, or both

Supply	Up to 7 years in prison, an unlimited fine, or both	Up to 14 years in prison, an unlimited fine, or both on indictment; and 6 months' imprisonment and a £5,000 fine on summary conviction	Up to 14 years in prison, an unlimited fine, or both	Up to 14 years in prison, an unlimited fine, or both	Up to life in prison, an unlimited fine, or both
Import or export[1]	Up to 7 years in prison, an unlimited fine, or both	Up to 14 years in prison, an unlimited fine, or both on indictment; and 6 months' imprisonment and a £5,000 fine on summary conviction	Up to 14 years in prison, an unlimited fine, or both	Up to 14 years in prison, an unlimited fine, or both	Up to life in prison, an unlimited fine, or both

[1] Under the Customs and Excise Management Act 1979, the specific offences are 'improper importation of goods', 'exportation of prohibited or restricted goods' and 'fraudulent evasion of duty', and the penalties can be found here.

Factors considered by the ACMD when making classification recommendations

The following factors outlined in *Table 6*, are considered by the ACMD when conducting classification decisions. The interaction and overlap between factors ensure a consistent process is applied when developing recommendations and preparing evidence-based advice.

Table 6: An overview of the factors considered by the ACMD when developing recommendations for Classification decisions. The table describes the main concepts utilised for guiding and assessing both decisions.

Factor	**Considerations by the ACMD**
International Control	There is no obligation for the UK to control a drug under the MDA, which has been scheduled under the UN International Drug Control Conventions. Provided the broad aims of the Convention are still being met, and no other obligations on international control decisions are being undermined and there is a clear rationale why control under the MDA is not appropriate, there is scope for the UK to conduct other regimes to provide controls that would also (dependent on substance) appear convention compliant (such as leaving those substances to be subject to the provisions of the Psychoactive Substances Act 2016). In practice, control under the MDA 1971 is the most common mechanism of ensuring UK Convention compliance. Examples include: • List of Narcotic Drugs Under International Control • United Nations Office on Drugs and Crime
UK control	Consideration to existing control under MDA or PSA. Also consider other legal controls including Consumer Protection Act, Cigarette Lighter Refill (Safety) Regulations 1999, the Novel Foods (England) Regulations 2018, and the Poisons Act 1972.

Related controlled substances	How similar substances have been previously classified (or not) by referring to previous ACMD advice
International and UK prevalence of use	Prevalence and incidence of substance use in the UK context and internationally. Examples include: • Office for Health Improvement and Disparities (OHID), including Early Warning System • Crime Survey for England and Wales (CSEW) • NHS England • United Nations Office on Drugs and Crime • Stakeholder engagement with research studies, public health authorities, forensic service providers, law enforcement or customs staff (drug seizures) and submitted sample analysis organisations.
Other international learning	Experience of harm and evaluation of control/lack of control in other countries (for example from the USA Drug Enforcement Administration (DEA) or the United Nations Office on Drugs and Crime.
Substance properties including chemical structure and pharmacological action as well as those of similar substances	Detailed in Table 2
Substance-related deaths and additional health harms	Detailed in Table 2
Social harms	Detailed in Table 3
Status as a medicine in humans or animals	UK Marketing Authorisation, or permitted to be manufactured as a pharmaceutical ‘Special’. Consideration of whether the medicine is prescribed widely or frequently, and whether there is a requirement for immediate accessibility.

	Sources may include: Medicine and Healthcare Products Regulatory Agency (MHRA), Veterinary Medicines Directorate (VMD), European Medicines Agency and consultation with the research community.
If a medicine, evidence of safety profile	For example, clinical trial and post marketing surveillance (sources may include Medicine and Healthcare Products Regulatory Agency (MHRA) and Electronic Medicines Compendium (EMC))
If a medicine, potential for diversion	Likelihood of individuals attempting to obtain the drug by diversion from legitimate sources, for personal use or to sell on.
Legitimate non-healthcare uses	For example, in manufacturing or industrial use (following appropriate consultation).
Need for enforcement powers	For example, with regards to importation/exportation. Likely need of a possession offence. Likely sources include Border Force, National Crime Agency and National Police Chiefs' Council.
Potential unintended consequences of control	Impact on specific groups or vulnerable populations (e.g. homeless populations). Potential for displacement to other substances. Impact on legitimate use (if a medicine). For example, enforcement, international evaluation of previous controls, feedback from Government departments and research community.

Reaching a classification recommendation

The process of making a recommendation on classification is complex, due to the number and diversity of factors considered. It begins with a review of the available evidence for the areas mentioned in *Table 6,* from which a harms assessment is produced. The ACMD considers actual, potential, and relative harms of the drug.

Factors considered by the ACMD will be dependent on their appropriateness for the particular substance being addressed. The quality and quantity of evidence available to the ACMD will vary by substance. For some substances such as novel psychoactive substances, there may be very limited evidence as the substance may have only recently been detected. Emerging evidence may lead to a recommendation being reviewed. The Council will review a given recommendation 10 years after publication, or earlier if indicated, depending on newly emerging evidence brought to the ACMD's attention by its monitoring functions and other sources.

Proposed recommendations are developed by an ACMD working group or sub-committee, with additional expertise on a particular substance being co-opted if indicated. The classification recommendation will be derived from careful consideration of the evidence and decisions will be made considering both the prevalence of use and the potential for harm. These recommendations and the supporting evidence are then reviewed by the ACMD Full Council, reaching a consensus view where possible.

When making recommendations the Council typically mention whether other substance forms are covered by the recommendation, for example:

- stereoisomeric forms;
- any ester or ether of a substance;
- any salt of a substance;
- any preparation or other product; and
- any preparation designed for administration by injection.

The final decision on control and classification is for government to take and may consider wider factors beyond the ACMD's remit.

Chapter 5: Making Scheduling Decisions

Where a drug has been controlled under the MDA, it requires a scheduling decision. Scheduling allows for the legitimate use of controlled substances for specific purposes, such as research or medical use. Of note, substances controlled by the PSA or a TCDO do not require a scheduling decision. Additionally, when the Government decides to control a drug under the MDA, scheduling advice from the ACMD is required.

Definitions of Schedules of the Misuse of Drugs Regulations (MDR) 2001

Schedule 1*: Drugs in Schedule 1 do not have a UK marketing authorisation as a medicine and may not therefore lawfully be prescribed, except under a Home Office Licence. They do not usually have any legitimate medicinal**, veterinary*** or non-medicinal**** use. Compounds in Schedule 1 may lack supporting safety data and/or have a high potential for abuse or physical harm such that the highest level of restrictions or control are considered necessary.

Schedule 2: Drugs in Schedule 2 have demonstrated medicinal or veterinary use but have the greatest risk of abuse, dependence and/or physical harm in the absence of restrictions on their availability. The risk of diversion from legitimate use is very high in the absence of controls over importation/exportation, possession, storage, prescribing and supply. All drugs within Schedule 2 must be stored according to Safe Custody requirements.

Schedule 3: Drugs in Schedule 3 may lead to moderate or low degrees of physical dependence. They are generally less likely to cause physical harm than drugs in Schedule 2. Risk of diversion from legitimate use is moderate or high in the absence of controls over importation/exportation, possession, storage, prescribing and supply. A subset of Schedule 3 drugs is exempt from Safe Custody requirements as a result of having a lower risk of diversion and/or for reasons of operational practicality.

Schedule 4 (Part I): Drugs in Schedule 4 (Part I) – historically but not exclusively from the benzodiazepine class – are usually considered to be associated with a lower risk of physical dependence and a lower potential for misuse than drugs in Schedule 3. The risk of diversion is moderate in the absence of controls over importation/exportation, or in the absence of controls over possession, prescribing and supply. Drugs in Schedule 4 (Part I) are exempt from Safe Custody requirements as a result of having a lower risk of diversion.

Schedule 4 (Part II): Drugs in Schedule 4 (Part II) are mostly anabolic steroids, growth hormones and nonsteroidal anabolic agents. They are exempted from the prohibition on possession. They are also excluded from the application of offences

arising from the prohibition on importation or exportation when imported or exported in person by that person for administration to him or herself.

Schedule 5: Preparations in Schedule 5 are differentiated from every other Schedule as they are characterised by their formulation – they are low concentration or low strength preparations of compounds scheduled elsewhere. The Controlled Drug has a concentration level or total amount per dosage unit set a specified maximum and/or is compounded with another material so as to prevent recovery or misuse of the active compound. Because of their formulation, Schedule 5 preparations are considered to have the lowest potential for misuse, the lowest risk of physical dependence and the lowest risk of diversion.

Schedule 5 preparations are exempted from the prohibition on importation, exportation and possession and are subject to only limited record-keeping requirements. The destruction of Controlled Drugs requirements do not apply. They are the only Scheduled preparations that may be classified as Pharmacy Only Medicines. When classified as Prescription Only Medicines, the duration of validity of prescriptions is not restricted to 28 days, as it is for other Scheduled drugs.

Additional notes

* Recommendations for Schedule 1 of the MDR may require an additional clarification under the Misuse of Drugs (Designation) Order 2015.

Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015
The clauses of Section 7(3) of the Misuse of Drugs Act 1971 permit medical use of Controlled Drugs, subject to Regulations, unless this is specifically outlawed by Section 7(4). The 2015 Designation Order and its amendments list the materials which are covered by Section 7(4).

Within the Designation Order, Part 1 of Schedule 1 specifies which materials are affected by reproducing the wording of the relevant control clauses of the MDA/MDR. As these include some generic controls, the scope of which covers legitimate medical pharmaceuticals, there is also a Part 2 of the Schedule which lists particular materials to be exempted from the Part 1 control so that they can remain available for medical use.

**the Human Medicines Regulation defines a ‘medicinal product’ as:

any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
any substance or combination of substances that may be used by or administered to human beings with a view to—
restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or
making a medical diagnosis.

***the Veterinary Medicines Directorate (VMD) has noted that a Veterinary Medicinal Product (VMP) is legally defined as:

any substance or combination of substances presented as having properties for treating or preventing disease in animals

any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis

**** Non-medicinal use could include, for example, usage in industry or agriculture

Factors to consider in scheduling decisions

Table 7: An overview of the factors considered by the ACMD when developing recommendations for Scheduling decisions. The table describes the main concepts utilised for guiding and assessing both decisions.

International control	Is the UK, as a signatory to the UN International Drug Control Conventions, obliged to control the drug? If so, what level of control is mandated by the drug's scheduling under these conventions? Consider that the UK usually follows international scheduling decisions.
Status as a medicine in humans or animals	Does the drug have a UK Marketing Authorisation, or is it permitted to be manufactured as a pharmaceutical Special? Consider that drugs without UK Marketing Authorisation will usually be placed in Schedule 1.
Use in industry, agriculture, cosmetics	Is the drug used in these or any other non-medical/veterinary fields? Consider the ramifications of scheduling on the use of such compounds in commercial, non-medicinal environments.
Classification under the Misuse of Drugs Act	Is the drug currently classified under the MDA or is it likely to be? Consider that there are some broad conventions in respect to classification. Class A and B drugs tend to be in Schedules 1 and 2. Class C drugs tend to be in Schedules 3 and 4 (Parts I and II).
Safety	Is safety established in short- and medium-term clinical trials and in post marketing surveillance? Is knowledge of safety derived only from observation of illicit use? How safe is the drug known to be?

	Consider that lack of knowledge of safety usually means that drugs are placed in Schedule 1. Where safety is known, consider that the dangers presented by the drug contribute to the determination of its listing in Schedules 2, 3 or 4; the most dangerous (in respect to adverse effects in clinical use and overdose potential and mortality) being placed in Schedule 2 and the least in Schedule 4.
Toxicity	Is the acute, chronic and overdose toxicity known? How dangerous is the drug in respect to physical and mental health? Consider that the toxicity of the drug contributes to the determination of its listing in Schedules 2, 3 or 4; the most dangerous being placed in Schedule 2 and the least in Schedule 4. Factors to consider in determining dangerousness include clinical tolerability, medium and long-term adverse effects and overdose toxicity
Behavioural effects	What is known of the effect of the drug on behaviour? Is the drug known to provoke dangerous, impulsive or aggressive actions? Consider that the behavioural toxicity of the drug contributes to the determination of its listing in Schedules 2, 3 or 4; the most toxic being placed in Schedule 2 and the least in Schedule 4.
Dependence potential	How readily do people become dependent on the drug? Is the drug physically or psychologically addictive, or both? Is the drug prone to misuse? What is known about antisocial or criminal behaviours associated with the drug or with drug-seeking behaviour? What is the likelihood of recovery from dependence on the drug? How unpleasant and physically dangerous is withdrawal from the drug? Consider that the dependence potential and dependence severity of the drug contribute to the determination of its listing in Schedules 2, 3 or 4; the most addictive being placed in Schedule 2 and the least in Schedule 4.

Diversion potential	How likely are people to attempt to obtain the drug by diversion from legitimate sources, for personal use or to sell on? Consider that the diversion potential of the drug contributes to the determination of its listing in Schedules 2, 3 or 4. Safe custody requirements of the different schedules should be appropriate to the potential for diversion
The need for controls on importation/exportation	Do the above factors mean that importation should be controlled so as to limit, identify, and allow seizure of shipments of the drug? How likely are people to attempt to obtain the drug by importation, for personal use or to sell on? How likely are people to attempt to profit from the exportation of the drug? Consider that the potential for uncontrolled import/export of the drug contributes to the determination of its listing in Schedules 2, 3 or 4. Controls on import/export of the different schedules should be appropriate to the potential for import/export. Consider that possession, importation, and exportation of drugs in Schedules 2, 3 and 4 Part I are offences under the Misuse of Drugs Act. There is no possession offence for drugs in Schedules 4 Part II and Schedule 5, and there is no importation/exportation offence for drugs in Schedule 5. Importation/exportation of drugs in Schedule 4 Part II is not an offence where the importation/exportation is carried out in person for administration to that person. However, unaccompanied importation (e.g. on-line purchases) and importing with intent to supply is still an offence. Most drugs in Schedule 4 Part II are typically Class C drugs. The exemption from possession (for personal use) regulations for Schedule 4 Part II drugs makes controls over importation/exportation of singular importance. Consider, the likely effects of criminalisation and the need for control on importation/exportation via on-line orders? Would the absence of a possession offence (alongside public health measure) be more effective than criminalising users? How likely are

	people to attempt to obtain the drug by importation via on-line purchases? How likely are people to attempt to profit from the exportation of the drug via on-line sales?”
Prescribing of the medicine	Is the medicine prescribed widely or frequently, or is there likely to be a requirement for immediate accessibility, such that restrictions on storage or supply could cause important operational problems? Consider that the factors listed above and below need to be balanced against operational needs in practice.
Chemical structure and pharmacological action of the drug	Is the drug a benzodiazepine and/or benzodiazepine receptor agonist? Is the drug an anabolic steroid; does it have anabolic properties? Consider that historically benzodiazepines (with some exceptions) have been placed in Schedule 4 part 1, and anabolic steroids in Schedule 4 part II.
Formulation of the drug	Is the drug a low-concentration or low-dose formulation of a Controlled Drug? Can the Controlled Drug element of the compounded formulation product be easily separated from other ingredients? Consider that low-concentration or low dose formulations may be placed in Schedule 5 when risks of dependence, toxicity and diversion are considered to be so low as to require minimal control over supply, storage and record keeping.

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