University of Glasgow

SEPS Guidance Note

(GN-CHEM18/2018)

Controlled Drugs and Precursors in Research

Introduction

The possession, use, supply and disposal of certain substances is controlled under the Misuse of Drugs Act 1971 and associated regulations including the Misuse of Drugs Regulations 2001 and The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2009. Controlled drugs are split into five groups which are listed in Schedules in the regulations. Drugs listed in each Schedule share common restrictions and requirements for supply, storage and licensing. Schedule 1 drugs are generally considered the most hazardous and are therefore subject to the most stringent restrictions with Schedule 5 drugs for the most part being low concentration preparations of other drugs and are least strictly controlled. Some examples of drugs falling into different Schedules are given below:

Schedule 1: Cannabis (including cannabis resin), ecstasy, mescaline, raw opium

Schedule 2: Cocaine, morphine, fentanyl, amphetamine, methylamphetamine, diamorphine (heroin), ketamine

Schedule 3: Temazepam, meprobamate, barbitone, tramadol

Schedule 4: Diazepam, N-ethylamphetamine

Schedule 5: Preparations containing low concentration of heroin, cocaine and other specified Schedule 2 drugs

For a complete list of the drugs in each Schedule it is recommended that the following resources are used; The Misuse of Drugs Regulations 2001 (Schedules 1-5) contains the full list of substances and categories of substances that are regulated. The regulations were subsequently updated by the Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2009 which includes some minor updates and reclassifications and both documents are required to correctly classify some substances. The regulations can be difficult to interpret in some cases and to assist, the Home Office also publish a user-friendly list of some of the most common controlled drugs and which Schedule they fall into which can be found online at https://www.gov.uk/government/publications/controlled-drugs-list--2

To help prevent the illicit production and sale of controlled drugs certain drug precursor compounds are also tightly regulated. These include both compounds that such as ephedrine that can be chemically altered to form controlled drugs and also some common laboratory chemicals used to carry out the process such as acetic anhydride (when supplied in large quantities).

Note: The classifications are reviewed regularly, and some controlled drugs may be moved to a different Schedule from time to time. It is the responsibility of the user to ensure that they regularly review stocks and take appropriate action in the event that a substance is reclassified under a different Schedule.

Note: This guidance only covers the use of controlled drugs in research projects, different requirements apply to other applications, for example the use of controlled drugs in veterinary medicine, clinical or dental work.

Purchase and Licensing Requirements (Possession)

Controlled Drugs

The purchase, storage and use of controlled drugs in any Schedule requires a specific license from the Home Office. However certain exemptions apply and the current guidance issued by the Home Office confirms that University research departments **do not** generally require a licence to possess and supply drugs in Schedules 2,3,4 (parts I and II) and Schedule 5. However, a license **would be** required to possess or supply drugs in Schedule 1 **or to produce**

controlled drugs listed in any Schedule. We recommend that anyone who wishes to engage in the production of controlled drugs contact SEPS for advice.

Licenses to possess controlled drugs in Schedule 1 are not held centrally by the University and a separate license is required by each management unit that wishes to undertake work using these substances. Once obtained the license covers the whole of the management unit named on the license and there is no time limitation applicable (i.e. an annual renewal is not required). Chemical suppliers will generally request a copy of the Home Office license before they will supply any controlled drugs. Note that in order to qualify for a license a fee is payable and all personnel with access to controlled drugs will be required to undergo a check by the Disclosure and Barring Service (DBS). This means that although the license applies to the School / Unit only certain named people will be permitted to work with controlled drugs.

Note: Any schools or units with "spin off" companies that carry out activities involving controlled drugs will not be covered by licenses owned by the University of Glasgow and must ensure that they hold a separate license.

Note: "Production" as an activity under the Misuse of Drugs Regulations 2001 is held to mean the creation of one substance from another (containing a controlled drug), even if the molecular structure of the controlled drug element remains unchanged. Therefore "dilution" of the drug content of a solution could be considered a "production activity" and may need to be licensed as such. This is most likely to be required for the production of reference standards and/or stock solutions.

Controlled Drug Precursor Chemicals

The supply of precursor chemicals (i.e. substances that can be used in the manufacture of controlled drugs) is also closely regulated in the UK. Regulation of precursor chemicals covers 23 substances which are further subdivided into three categories based on how they are used in the production of controlled drugs (see appendix 1 for a complete list):

Category 1 (Most sensitive substances)

Category 2 (Less sensitive substances and precursors)

Category 3 (Bulk chemicals that can be used in drug production e.g. solvents)

The legislation excludes medicinal products for human use, but covers all natural products and preparations (or mixtures) containing at least one Scheduled substance, provided that they can be extracted by 'readily applicable or economically viable means.

Schools or units holding (or wishing to purchase) category 1 drug precursors require to hold a license from the Home Office, other precursors may or may not require a license depending on the amount held by the unit. Before a supplier can provide any quantity of a category 1 precursor the School / Unit will have to complete a declaration of specific use whether or not a license is required. These generally take the form of a standard form and are straightforward to complete.

Note: Any schools or units with "spin off" companies that carry out activities involving category 1 substances will not be covered by licenses owned by the University of Glasgow and must ensure that they hold a separate license.

Annual Returns

The Home Office requires license holders to provide them with an annual return by the 31st of January each year covering their use of controlled drugs to fulfil the government's commitments to the UN International Narcotics Control Board. In general licensed end users will only need to submit an e-mail to the address below stating that they are providing a "nil return".

annualdrugreturns@homeoffice.gsi.gov.uk

Licensed Users within the University who have permission to possess controlled drugs may be required to submit a more detailed annual return using the online form hosted on the Home Office website if they hold stocks of certain substances. The full list is available on the form but for convenience all of the Schedule 1 substances that require an

annual return have been reproduced in Appendix 2* other susbtances in Schedule 1 will be covered by a standar "nil return". Remember that for research purposes in Universities licenses are not generally required for possession of substances in other Schedules) and therefore for possession of drugs in Schedules 2-5 no return will be required.

*Correct as of 01 September 2018

Note: While annual returns may be required for manufacture and supply of some controlled drug precursors they are generally not required for possession of these substances.

Surrendering of Licenses

Where a unit or school no longer intends to handle controlled drugs (and is unlikely to do so again in the future) the controlled drugs license should be formally surrendered. This can be achieved by fully completing the Home Office form which can be found using the link below. The form should include details of any stocks held, confirmation of destruction, record keeping etc.

https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns#how-do-i-surrender-my-licence-or-registration

Safe Storage and Security

Storage Areas

All controlled drugs should be stored securely to help prevent theft, loss and to prevent unauthorised personnel having access to them. It is recommended that controlled drugs in Schedules 1-3 (and category 1 precursor chemicals) should be stored in a secure area when not in use and that controlled drugs in Schedules 4 and 5 are subject to the same storage arrangements so far as is reasonably practicable. General considerations are as follows:

- External doors and windows should be fitted be locked or otherwise inaccessible. This may not be relevant in areas where windows do not open or when the laboratory is located on an upper floor but care should be taken to ensure security is not compromised by scaffolding or other access routes during maintenance.
- An alarm system should be considered which is monitored locally or off-site. Care should be taken to inform anyone monitoring the alarm of the arrangements in the event of an unexpected activation, generally this will involve informing the police.
- An agreed set of Standard Operating Procedures (SOPs) should be implemented to ensure that controlled drugs are handled and stored appropriately and that suitable management systems are in place to reduce the risk of unauthorised access, loss or theft.

While there are no specific security arrangements for storage of controlled drugs in laboratories in higher education, the guidance set out in The Misuse of Drugs (Safe Custody) Regulations 1973 and the Security Guidance published by the Home Office provide useful guidelines to prevent loss or theft of controlled drugs. They recommend that controlled drugs are stored in a locked strong room, safe or cabinet depending on the quantity (specifications for these are available in the associated Home Office Guidance). They also recommend that the door to the laboratory or storage area where controlled drugs and precursors are kept should be fitted with a lock that is operated by a keypad, key or digital locking system. The lock should be engaged at all times including out of hours to prevent unauthorised access.

Substances that are stored at reduced temperature (e.g. in a refrigerator) should be stored in a locked fridge or freezer or in a locked container inside where practical. Note that if a locked container is used then precautions should be put in place to prevent the theft of the container itself (securing the container to an immovable part of the appliance is usually the most appropriate solution).

Note: The Home Office recommend that controlled drug cabinets / safes are locked using a combination lock or similar system. This helps to avoid the need to make security arrangements for keys, access card etc.

Standard Operating Procedures (SOP)

As noted above Licensees will require to put in place standard operating procedures (SOPs) covering all activities involving controlled drugs. While only Schedule 1 drugs and category 1 precursors require to be licensed for research. We recommend that these procedures are applied to all activities involving controlled drugs as a matter of good practice.

- Check the application of the regulation to your activities to ensure that procedures and storage arrangements are compliant with the required legislation. In particular care should be taken to highlight any changes in the Schedule to which a controlled drug has been assigned.
- Orders and arrangements for receipt of controlled drugs should be clearly detailed along with contact details for responsible person(s) and the procedures / authorisations required to order controlled drugs or controlled precursors.
- Clear processes for the acceptance of deliveries including logging of deliveries and secure storage in the interim before they are transported to a secure storage area.
- Details of record-keeping process including details of the type, amount and usage of controlled drugs, auditing and cross-checking of stocks against receipt, use and disposal records.
- Access procedures for storage areas and laboratories should be detailed including security arrangements, personnel with access, removal of access privileges and signing out procedures.
- Procedure for destruction / removal of controlled drugs, this process should include a suitable record which should be countersigned by the person / organisation carrying out the destruction.
- Investigation of theft, loss or other incidents
- Reporting procedures for theft, loss or other incidents

Note: Remember to ensure that the required risk assessments and CoSHH assessments are in place for any activities involving controlled drugs in any Schedule.

Audits and Discrepancies

In order to maintain control of controlled drugs (and category 1 precursors) a detailed and accurate controlled drugs register should be accurately kept and should be maintained for at least 2 years after the last disposal of any material. The log should contain the following information for each controlled substance:

- Name of substance
- Date of purchase and supplier
- Quantity purchased
- Quantity used, removed or disposed of and date of transaction
- Current stock level
- Name and signature of person using controlled drugs

Controlled drug stocks should be audited regularly (monthly is recommended) to ensure that the amount held is correct after accounting for normal use and disposal). Audits should be carried out monthly at which time the controlled drugs register will be checked to ensure that remaining stocks can be reconciled against the original quantity purchased, usage and disposal to ensure that no discrepancies are identified.

Note: In the event of any discrepancies being highlighted in stocks of controlled drugs (any Schedule) or category 1 precursors (e.g. missing substances, thefts) a local investigation should take place. if the discrepancy cannot be resolved it should be reported to the Home Office using this form: https://www.gov.uk/government/publications/thefts-and-losses-report-form-december-2011

Note: In the event that a significant amount of a Schedule 1 Drug or Category 1 precursor substance is lost or stolen the incident should be reported to the Home Office immediately. It may also be prudent to report this to the police.

Disposal / Destruction of Controlled Drugs

It is a legal requirement for stocks of controlled drugs to be managed appropriately when they are no longer required. Specific rules apply to the destruction and/or disposal of controlled drugs depending on the Schedule in which they are listed. When no longer required for research (or other uses) controlled drugs should be destroyed or disposed of as follows:

Drugs Listed in Schedule 1

Destruction of Schedule 1 drugs must be carried out within the University as the licenses issued for their use do not permit them to be handed over to another person or organisation. Destruction must be witnessed by a person who has been specifically authorised by the Home Office (or by a Police Officer). The person who witnesses the destruction **must not** have any involvement of the day-to-day use or record keeping of the drugs and the process must be carried out in accordance with a written procedure.

Note: A license to purchase, store or use drugs in Schedule 1 does not convey the authority to witness their destruction. This requires specific authorisation from the Home Office. Note that Schedule 1 controlled drugs cannot be disposed of via a licensed waste contractor.

Drugs listed in Schedule 2

Drugs listed in Schedule 2 may be disposed of using one of two methods; destruction via a licensed waste contractor or destruction in house if witnessed by a police officer:

1. **Destruction via a Licensed Waste Contractor**
   The University is permitted to transfer Schedule 2 drugs to other parties. It is therefore permissible to engage a suitable waste contractor to remove these materials for off-site destruction. It is essential that the contractor used to transport and destroy this material is licensed to do so. This means that they **must** hold the necessary licenses form the Home Office to possess Schedule 2 drugs and the authority to witness their destruction. In addition to this they must be registered waste carriers and the destruction must be carried out at a facility with the required waste management licence / permit. This service is currently carried out by the University Clinical Waste Disposal Company.
2. **Destruction in house in the presence of an authorised witness.**
   Destruction of Schedule 2 drugs obtained and used for research within the University can be destroyed in-house if witnessed by a Police Officer. As the University does not require a license to use these drugs for research purposes the Home Office cannot authorise a person within the University to witness the process meaning that only a police officer may serve as the witness.

It should be noted that, whilst certain professionals within the NHS / Healthcare community can be designated as authorised witnesses for the disposal of drugs in these environments this mechanism does not currently extend to the authorisation of veterinary surgeons. As a result, veterinary surgeons are not generally permitted to witness the destruction of Schedule 2 drugs unless specifically authorised to do so.

Drugs Listed in Schedules 3 and 4

Unless the Schedule 3 or 4 drug has been produced in-house it is permissible it is permissible for these materials to be destroyed in-house without the need for an authorised witness to be present. These substances can also be disposed of by the University's authorised waste contractor in the same manner as for Schedule 2 drugs.

Drugs in Schedule 5

Drugs in Schedule 5 can always be destroyed in house without the need for an authorised witness to be present. These substances can also be disposed of by the University's authorised waste contractor in the same manner as for Schedule 2 drugs.

Drug Listed in Schedule	Disposal / Destruction Route			
	Licensed Waste Contractor	In-House with Home Office authorised witness	In-house with police officer as witness	In house, no authorised witness required
Schedule 1	No	Yes	Yes	No
Schedule 2	Yes	No	Yes	No
Schedule 3*	Yes	Yes (Not required)	Yes (Not required)	Yes
Schedule 4*	Yes	Yes (Not required)	Yes (Not required)	Yes
Schedule 5	Yes	Yes (Not required)	Yes (Not required)	Yes

*Unless the drug has been produced in-house.

References

- Misuse of Drugs Act 1971
- The Misuse of Drugs (Safe Custody) Regulations 1973
- The Misuse of Drugs Regulations 2001
- The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2009
- Psychoactive Substances Act 2016
- Guidance for the safe custody of controlled drugs and drug precursors in transit (Home Office DLCU, 2016)
- Security guidance for all existing or prospective Home Office controlled drug licensees and/or precursor chemical licensees or registrants (Home Office DLCU, 2016)

Further Information

Further information on the management of controlled drugs can be found on the Home Office website but in the event that a specific issue arises not covered by the regulations or guidance please contact the appropriate adviser in the Safety and Environmental Protection Service. **If you wish to produce controlled drugs listed in any Schedule please seek advice from SEPS.**

General Office: 0141 3305532
Biological Safety Adviser: 0141 3307105
Chemical Safety Adviser: 0141 3302799
Environmental Adviser: 0141 3305854

Appendix 1: Drug Precursor Chemicals

Category	Substance	End User (UK)	Trade Within EU	Trade Outwith EU
1	1-phenyl-2-propanone (BMK) 3-4 Methylenedioxy-Phenylpropan-2-one (PMK) Alpha-phenylacetoacetonitrile (APAAN) Chloroephedrine Chloropseudoephedrine Ephedrine Ergometrine Ergotamine Isosafrole Lysergic Acid N-acetylanthranilic Acid Norephedrine Piperonal Pseudoephedrine Safrole	License required for any quantity	License required for any quantity	License required for any quantity
2a	Acetic Anhydride	Registration required for use and supply of more than 100 litres per calendar year	Registration required for use and supply of more than 100 litres per calendar year	Registration required
2b	Phenylacetic acid Potassium permanganate Anthranilic Acid Piperidine	No registration required for end users.	No registration required for end users.	Registration required
3	Acetone Diethyl ether Hydrochloric acid Methylethyl ketone (MEK) Sulphuric acid Toluene	No registration required for end users.	No registration required for end users.	Registration may be required for export above certain thresholds

Appendix 2: Schedule 1 Controlled Drugs Requiring an Annual Return

- Cannabis (including cannabis oil and cannabis resin)
- Cathinone
- Coca leaf
- N,N-dimethyltryptamine (DMT)
- Lysergic acid diethylamide (LSD)
- 3,4-Methylenedioxyamphetamine (MDA)
- 3,4-Methylenedioxy-N-ethylamphetamine (MDEA)
- 3,4-Methylenedioxymethamphetamine (MDMA)
- Methcathinone
- Opium (raw)
- Psilocine
- Tetrahydrocannabinol (including delta-9-THC)