

# **SAFE AND SECURE HANDLING OF MEDICINES**

## **Section 8.1. Controlled Drugs (CDs) - Introduction**

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### 8.1.1. Controlled Drugs (CDs) - Introduction

Controlled Drugs (CDs) are those which are restricted in use by the Misuse of Drugs Act 1971 and associated Regulations. This is due to their desirability and potential for diversion, misuse and harm. CDs are essential in modern clinical care, and many do have a valuable medicinal purpose, and the legislation aims to ensure that prescribers and other professionals are not obstructed or prevented from treating patients appropriately.

In the Code of Corporate Governance, it states that ‘all NHS Tayside staff and individuals acting on NHS Tayside’s behalf, are responsible for conducting NHS Tayside’s business professionally, with honesty, integrity and maintaining the organisation’s reputation and free from bribery.’ This includes responsibility for the safe and secure handling of medicines including CD’s.

Healthcare professionals are responsible for CD governance under their registrations (GMC, NMC, GPhC etc).

[The Misuse of Drugs Regulations 2001](#) categorises CD’s into 5 Schedules and restrictions are applied depending on which Schedule the CD is in.

**Schedule 1 CDs:** hallucinogenic drugs such as lysergide and mescaline and products advertised as ‘legal highs’. Virtually all drugs listed in Schedule 1 have no recognised medicinal use. The production, possession and supply of Schedule 1 CDs are limited to research or other purposes considered of public interest. Only certain persons can be licensed by the Home Office to possess them for these purposes. Practitioners and Pharmacists may not lawfully possess Schedule 1 CDs except under licence from the Home Office.

**Schedule 2 CDs:** includes more than 100 drugs such as high strength opiates, ketamine, the major stimulants, secobarbital and amphetamine and lisdexamfetamine:

- **Supply:** Restricted to licensed wholesalers, practitioners, hospitals and registered pharmacies. Wholesalers are permitted to supply only to a person authorised to possess CDs. Practitioners can supply to persons authorised to possess CD’s and to their patients. Hospitals may supply patients, wards and practitioners. Pharmacies may supply on receipt of a valid prescription or signed order. Additional prescription writing requirements exist ([see section 8.4 Prescribing Controlled Drugs](#)). Schedule 2 CD’s cannot be included in a Patient Group Direction (PGD).
- **Record:** A record of all Schedule 2 CDs obtained and supplied must be kept in a register, the form of which must comply with the relevant Regulation.
- **Storage:** Schedule 2 CDs (except quinalbarbitone) are subject to safe custody requirements (The Misuse of Drugs [Safe Custody] Regulations 1973, amended 2007). They must be stored in a locked receptacle, such as an appropriate CD cabinet, which can only be opened by the person in lawful possession of the CD or a person authorised by them.
- **Destruction:** The destruction of Schedule 2 stock CDs must only take place in the presence of an appropriately authorised person known as an Authorised Witness (AW). Schedule 2 CDs must be rendered irretrievable prior to disposal using a CD destruction kit. Please see [section 8.8](#) for further information on destruction of stock and patients own Schedule 2 CD’s in different healthcare settings.

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**Schedule 3 CDs:** contains a number of substances that are perceived as being open to abuse, but less likely to be so than Schedule 2 CDs. It contains a number of synthetic opioids together with other substances including temazepam, midazolam and gabapentinoids.

- **Supply:** The Regulations concerning supply (and additional prescription writing requirements) are similar to Schedule 2 CDs. Midazolam is the only Schedule 3 CD that in certain circumstances can be included in a PGD.
- **Record:** There is no statutory requirement to record the supply of Schedule 3 CDs.
- **Storage:** The majority of Schedule 3 CDs are exempt from safe custody requirements except temazepam, flunitrazepam, buprenorphine and diethylpropion. These must be stored in a locked receptacle such as an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by them.
- **Destruction:** The requirements relating to the need for an AW for destruction do not apply to Schedule 3 CDs. Please see [section 8.8](#) for further information on destruction of stock and patients own Schedule 3 CD's in different healthcare settings. Schedule 3 CDs must be rendered irretrievable prior to disposal using a CD destruction kit.

**Schedule 4 CDs:** Split into two parts:

- **Part 1** (CDs- Benzodiazepines) contains most of the benzodiazepines (with the exception of flunitrazepam, midazolam and temazepam which are Schedule 3), plus eight other substances including zolpidem and zopiclone.
- **Part 2** (CD Anabolic steroids) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoceptor stimulant) and growth hormones (5 polypeptide hormones).

Drugs in Part 1 (CD -benzodiazepines) are subject to full import and export control and a Home Office licence is also required for the importation and exportation of substances in Part 2 (CD Anabolic steroids) unless the substance is in the form of a medicinal product and is for personal use / administration.

- **Supply:** Supply is restricted to supplies against practitioner's prescriptions or in accordance with PGDs. There are no additional requirements as to the form of prescriptions other than those that apply to all Prescription Only Medicines (POMs).
- **Record:** There is no statutory requirement to record the supply of Schedule 4 CDs.
- **Storage:** Schedule 4 CDs are exempt from safe custody requirements.
  
- **Destruction:** The requirements relating to the need for an AW for destruction do not apply to Schedule 4 CDs. Please see [section 8.8](#) for further information on destruction of stock and patients own Schedule 4 CD's in different healthcare settings. Schedule 4 Part 1 CDs must be rendered irretrievable prior to disposal using a CD destruction kit.

**Schedule 5 CDs:** Schedule 5 contains preparations of certain CDs, e.g. codeine, dihydrocodeine, pholcodine, morphine, which are exempt from full control **when present in** medicinal products of low strengths.

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- **Supply:** Certain CDs in Schedule 5 are available for over-the-counter sale in registered pharmacies. It is for the pharmacist to use their professional judgement to determine the appropriateness of any supply and be alert to potential misuse. The Schedule 5 CD POMs can only be supplied in accordance with a valid prescription or PGD.
- **Record:** There is no statutory requirement to record the supply of Schedule 5 CDs.
- **Storage:** Schedule 5 CDs are exempt from safe custody requirements.
- **Destruction:** The requirement to have an AW for destruction or the requirement for denaturing does not apply to Schedule 5 CDs.

See [Misuse of Drugs Regulations 2001](#) for further information.

### 8.1.2. Controlled Drugs (CDs) - The Controlled Drugs Team

The Controlled Drugs Accountable Officer (CDAO) is responsible for all aspects of CD management within the organisation in accordance with the [Health Act 2006](#) and the [Controlled Drugs \(Supervision of Management of Use\) Regulations 2013](#). The CD team supports the CDAO by:

- Developing standards and monitoring the purchase, storage, prescribing, dispensing, administration and destruction of CDs.
- Inspecting/auditing premises across the Health Board area including GP Practices, Hospital Pharmacies, Wards and Theatres
- Ensuring concerns and incidents, including significant events, involving CDs are fully investigated.
- Ensuring that adequate processes are in place, which conform to the legal requirements, to destroy CDs which are out of date or no longer required.
- Gathering and sharing intelligence with relevant bodies, for example, Police Scotland, NHS Scotland Counter Fraud Services and the professional regulatory bodies.

**CDAO:** Responsible for the safe management of CDs. Determine priorities and strategy.

**Lead Pharmacist:** Manages the CD Team and provides direction and support to the members. Direct link to CDAO.

**Specialist Pharmacist:** Responsible for the day-to-day operational activities of the CD team. Develops and reviews policies and procedures to ensure safe and effective use of CD's within NHS Tayside. Ensures incidents and concerns involving CDs are fully investigated. Provides advice, support and training on legislation and best practice. Acts as an authorised witness in the destruction of CD's.

**CD Inspection Officer:** Carries out inspections/audits of premises and compiles inspection/audit reports., Provides advice, support and training on legislation and best practice, investigates incidents and concerns, Acts as an Authorised Witness in the destruction of CDs.

**Pharmacy Department Administrator:** Provides admin support to the CD Team.

**Authorised Witness (AW):** Authorised by the CDAO to witness the destruction of Schedule 2 CDs.

The CDAO and the CD team are based at King's Cross Hospital and can be contacted via:

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Telephone: 01382 835153 (internal ext 71374) OR E-mail: [tay.cdteam@nhs.scot](mailto:tay.cdteam@nhs.scot)

### 8.1.3. Controlled Drugs (CDs) - Attractive/Desirable Medicines

All CD's have the potential to be misused. A number of other medicines, which are not CD's, also have the potential to be misused and these include, but are not limited to corticosteroids, laxatives, sedative antihistamines, decongestants and weight loss medicines.

All staff should be aware of the behaviours associated with seeking medicines for misuse or onward misappropriation. Changes in an individual's behaviour can be a warning sign, for example, a lack of concentration, unexplained absences.

Any suspicious behaviour should be reported immediately to the relevant person, for example, staff members line manager.

Staff members should be vigilant for signs of misappropriation of medicines for example unexplained loss of stock or inappropriate ordering patterns of CD's or other medicines. Any misappropriation of medicines will not be tolerated within NHS Tayside. Theft of medicines is a serious criminal offence and will be reported to Police Scotland.

See [section 8.7.3](#) for further information on what to do if there is a suspected breach of security or loss of medicines.

Current lower schedule CD's and other medicines liable for misuse are (not an exhaustive list):

All benzodiazepines, including:

- Diazepam (Schedule 4 part 1)
- Lorazepam (Schedule 4 part 1)
- Lormetazepam (Schedule 4 part 1)
- Midazolam (Schedule 3)
- Nitrazepam (Schedule 4 part 1)
- Oxazepam (Schedule 4 part 1)
- Temazepam (Schedule 3)

Analgesics:

- Codeine (Schedule 2 / 5)
- Dihydrocodeine (Schedule 2/5)
- Gabapentin (Schedule 3)
- Ketamine (Schedule 2)
- Morphine (Schedule 2 / 5)
- Pregabalin (Schedule 3)

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- Tramadol (Schedule 3)

Hypnotics:

- Zopiclone (Schedule 4 part 1)
- Zolpidem (Schedule 4 part 1)

Other Drugs:

- The type of drugs potentially misused by patients/staff is continuously changing. Examples include, but are not limited to corticosteroids, growth hormones, laxatives, sedating antihistamines, decongestants, medicines for erectile dysfunction and medicines for weight loss.

Please refer to:

- [List of most commonly encountered drugs currently controlled under the misuse of drugs legislation](#)
- [Alcohol, Drugs and Other Substance Use Policy and Procedures](#) (Staffnet link)

**References used in this section include:**

[Controlled Drug Accountable Officer Network Scotland's A guide to Good Practice in the Management of Controlled Drugs in Primary Care Scotland](#)

[Misuse of Drugs Regulations 2001](#)

[Misuse of Drugs \(Safe Custody\) Regulations 1973](#)

[Controlled Drugs \(Supervision of Management of Use\) Regulations 2013](#)

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