THE SUPERVISION OF THE MANAGEMENT AND USE OF CONTROLLED DRUGS

Introduction

Scope

1. This JSP 950 leaflet outlines the role of the MOD's Controlled Drug Accountable Officer (CDAO) and associated roles and responsibilities for all personnel that are involved in the management and use of Controlled Drugs (CD). For the purposes of this policy leaflet, the term Controlled Drug encompasses those drugs classed within the MOD as Accountable Drugs (AD)[1] unless specifically stated otherwise. This policy is in accordance with UK legislation, but will detail where military-specific variation exists.

Aim

2. The aim of this leaflet is to define the responsibilities of commanders, medical staff and other relevant individuals in respect of the supervision and management of CDs. It also outlines the legislative requirements and places them in a military context.

Background

3. As part of the response to The Shipman Inquiry - Fourth Report into the management of CDs, the Government introduced The Controlled Drugs (Supervision of Management and Use) Regulations 2006. The aim of these regulations was to strengthen the governance arrangements for the use and management of controlled drugs. As a result of the Health and Social Care Act 2012, the 2006 regulations have been revised to reflect the changes in the NHS in England. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force in England and Scotland[2] on 1 Apr 13 and listed the MOD as a Designated Body.

4. It is recognised that CDs are essential to modern clinical care. This policy augments existing governance arrangements to ensure that CDs are managed and prescribed safely and effectively to minimise poor practice, patient harm, misuse and misappropriation. MOD policy on the routine management of CDs, JSP 886 Defence Logistic Support Chain Manual Vol 6 Part 6 Chapter 4, provides the underpinning requirements to support the CDAO function and the detail required to support the development of SOPs.

Definitions

5. There are a number of terms from the new legislation used throughout this policy and for ease they are defined here:

   a. **Controlled Drug**. Controlled drugs are any substance or product that is listed in Schedules 1 to 5 of the The Misuse of Drugs Regulations 2001 and subsequent amendments and regulations. The schedules correspond to the drug's relative therapeutic usefulness and misuse potential.

[1] CDs and ADs can be found listed at JSP 886 Vol 6 Part 6 Chapter 4 Annex A. Note that there are a number of ADs in the MOD that are not legally classed as CDs.
[2] Wales and NI are in the process of developing their own existing and equivalent legislation; it is unlikely to be significantly different from that in England and Scotland. However, after consultation with the devolved administrations, the MOD will follow this policy leaflet across all boundaries, including overseas.

b. **Responsible Body**. All organisations defined in Regulation 6 of the 2013 Regulations that appear to be directly/indirectly concerned with the provision of healthcare and may carry out activities that involve the supply or administration of CDs, to have powers of inspection in relation to the management/use of CDs, or any other public/local authority whose responsibilities relate to identifying, considering or taking action relating to issues relating to the management/use of CDs.

c. **Controlled Drug Designated Body**. All organisations defined in Regulation 7(1) of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 are Designated Bodies. These are Responsible Bodies that are required to appoint a CDAO for their organisation.

d. **Local Intelligence Network (LIN).** LINs' duties and functions are set out in Regulations 14–16 of the 2013 legislation. LINs are to assist responsible bodies in the identification and consideration of concerns and incidents where action may need to be taken in respect of the safe management of CDs. These include a duty to co-operate with other LIN members in identifying cases where action may be appropriate, what the best course of action is and then putting it into effect. The regulations expressly state that LIN members can share information and intelligence, including personal confidential information where justified, without breaching the Data Protection Act.

Legislation

The MOD as a Designated Body

6. In accordance with The Controlled Drugs (Supervision of Management and Use) Regulations 2013 "the headquarters in England (and Scotland) of regular or reserve forces" is a Designated Body. Both the Health Act and the 2013 Regulations state that the Designated Body is required to provide the CDAO with the resources (financial or otherwise) necessary to carry out these responsibilities.

7. As Defence Authority[3], the Surgeon General has a responsibility to ensure that the MOD, as a Designated Body, has systems in place for the safe and effective management and use of CDs, adequate governance for the CDAO's conduct and for registering that individual with the Care Quality Commission (CQC).

8. Part 2 of the 2013 Regulations states that each Designated Body must appoint a CDAO who must be a "fit, proper and suitably experienced person" (Reg 8(1)). The CDAO must have credibility with health and social care professionals within the organisation and with other organisations and have sufficient seniority to be able to take action regardless of how a concern is raised. A CDAO must meet three conditions for appointment:

a. A senior officer (ie OF6 or superior rank).

b. The CDAO must be an officer or employee of the organisation concerned.

c. The CDAO should not "prescribe, supply, administer or dispose of controlled drugs" as part of their duties (Regulation 8(8)) or only exceptionally. An organisation can continue to nominate and appoint a CDAO who has occasional, exceptional need to use controlled drugs (for example, in emergencies). Where this is the case, their use of controlled drugs at that organisation should be open to the scrutiny of another person to whom they are answerable.

[3] The department's 18 Defence Authorities set rules and standards to shape delivery of key functions that cut across Defence and which are critical to Defence outputs (Defence Authorities).

9. In order to meet the above requirements at para 8, SG has nominated **Head of Medical Strategy and Policy** as the CDAO**.** They are responsible to SG as Senior Executive Officer of the Designated Body. The roles and responsibilities are laid out in more detail at Annex A. The role of the accountable officer supports, but does not replace, the mandatory responsibility of commanding officers with respect to the proper management of medical materiel.

Deputy CDAO

10. To maximise governance and reporting systems already in place, a deputy CDAO has been appointed to deliver the key roles and responsibilities. This is SO1 Pharmacy, HQSG (SGACDS StratPol-PharmSO1@mod.uk) and is the main POC for all CD enquiries.

11. The Deputy CDAO will:

a. Attend meetings to represent MOD eg CQC National CD Group, NICE and Home Office.

b. Prepare an annual report for the CDAO to present to SG, IG and the CQC to inform the DMS quality assurance process.

c. Provide biannual prescribing reports to cover specific and current issues.

d. Inform CQC of any changes to the nominated CDAO.

Subordinate Accountable Officers (SAO)

12. **Delegated Authority**. In order for the CDAO to undertake their responsibilities efficiently, the MOD has delegated authority for the management of CDs to the Chain of Command as follows:

a. Navy Command.

b. HQ Army.

c. Air Command.

d. PJHQ.

e. LCS – Medical Supplies Team.

f. DPHC (incl DDS)[4].

g. DMG[5].

h. HQ DSF.

13. **Responsibilities.** Each HQ/Command listed above is to ensure that:

a. A SAO is nominated and a signed copy of the TORs at Annex B is sent to SO1 Pharm, HQ SG.

[4] This is an internal policy and all overseas MTFs are required to comply with this policy. There is no requirement to ensure that the same arrangements are in place for non-UK healthcare providers eg German hospitals, Polyclinics in Cyprus.
[5] MDHUs are to conform to host Trust arrangements and are to only report by exception.

b. The nomination follows the same principles stated above at para 8 for the MOD's CDAO. They should be an individual at OF4/5 or civilian equivalent grade who has a thorough knowledge of best practice in relation to the management and use of CDs. This individual does not necessarily have to have a clinical background.

c. The SAO can delegate tasks to nominated individuals particularly if this is required to obtain specific subject matter expertise or to avoid a conflict of interest.

d. They review all occurrences and/or Significant Events (SE) relating to CDs and submit a CD occurrence report on a quarterly basis to SO1 Pharm HQ SG using the template at Annex C. All major issues of concern are to be sent to the CDAO or their deputy at the earliest opportunity.

e. An annual summary report is to be sent to the Deputy CDAO by 31 Mar. This is to include a summary of the occurrence reports for the year, copies of any external/internal inspections, audit or investigations, a statement that SOPs[6] are in place and up to date. A template is at Annex D.

Local Intelligence Networks

14. Given the scattered nature of UK Armed Forces bases across the UK and overseas, the MOD will have difficulty linking into all NHS LINs. However, LINs are important to share concerns and information and also to gather local intelligence on CD matters. Attendance at LINs by regional representatives is encouraged, particularly in the more densely populated military areas. Where appropriate, individual occurrence reports pertaining to specific UK locations are to be sent to an appropriate Local Area Team LIN, the identification of which will need to be determined locally.

15. The Senior Pharmacist Group meets quarterly and will act as a focus for all internal MOD CD matters.

Governance and Assurance

Reporting Requirements

16. Subordinate Accountable Officers are to ensure that all CD related incidents are recorded as soon as possible on the automated Significant Events Reporting system and submit a quarterly occurrence (Annex C) and Annual (Annex D) Report to SO1 Pharm, HQSG. The CDAO will submit an annual report to IG, SG and the CQC.

Assessing and Investigating Concerns

17. The CDAO and subordinates must ensure arrangements are in place to assess and investigate concerns. If, following initial assessment, the SAO considers the issue is more than an administrative anomaly and further investigation is required, they can investigate themselves, task another individual(s) from the MOD or if appropriate, request another responsible body to investigate or form a joint investigation team[7]. Another responsible body could include another designated body, regulatory body, the MOD/Service police. A record must be made of requests for assistance made to or from another responsible body in relation to an investigation and any assessment or investigation carried out on behalf of another designated body.

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[6] Further guidance on SOPs for CDs is encompassed in Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064824. In Scotland, guidance on SOPs for CDs can be found in CEL(2004)14 – Safer Management of Controlled Drugs – Standard Operating Procedures. Available from: http://www.sehd.scot.nhs.uk/mels/CEL2007_14.pdf

[7] The investigation may result in a need for advice, support, mentoring or training from an appropriate source.

Reporting Incidents

18. Personnel reporting CD issues or concerns are to use the automated Significant Events Reporting system and are to ensure that when classifying the event at Part One, they tick that it involved a Controlled or Accountable Drug. Personnel are also to use the term “controlled drug” or “CD” in the free text when describing the event.

19. The Quarterly Occurrence Report (Annex C) is to state the number of CD SEs raised in that quarter and can be used to provide further detail as required (a summary of each CD related SE is not required). If a CD incident has not been raised as a SE then it must be reported quarterly.

20. It is worth noting that personnel are often too concerned with safe custody and documentation and forget that clinical safety is a higher risk. From the NRLS[8] medication incidents the wrong dose is the most common incident resulting in death as a result of prescribing CDs. Examples of key areas to monitor are:

a. Incorrect or excessive prescribing (dose, quantity, and frequency).

b. Administration/documentation including poor accounting.

c. Security breaches.

d. Loss / breakages.

e. Use of antidotes.

f. Dispensing errors.

Governance

21. A designated body must monitor the activities of the CDAO (and SAO) to ensure that their responsibilities are discharged and must, after appropriate consideration, remove the nominated accountable officer if the individual no longer meets the requirements at Para 8; or if they are considered unfit to fulfil the function through, for example, breach of duty.

22. Facilities that hold CDs should already be subject to inspections as part of existing clinical governance or logistic support arrangements. All levels of Command should undertake periodic inspections of premises used in connection with the management or use of CDs, especially as they are not routinely subject to inspections by other regulatory bodies eg CQC or General Pharmaceutical Council. Each SAO should include evidence to support the following[9] in their Annual Reports:

a. SOPs are in place for the management and use of CDs.

b. An audit of CD management systems has been undertaken within 3 years.

Operations and Exercises

23. **Operations**. The role of the CDAO/SAO assumes a degree of continuity and stability in terms of both healthcare delivery and personnel that is at odds with the deployed environment.

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[8] National Reporting and Learning System.
[9] Criteria based on Element 2 of the Healthcare Commission Core Standard C4d.

Whilst it is impractical to identify an SAO for each operational theatre, or even to delegate that role from PJHQ, it is the responsibility of the theatre medical commander to ensure that there are robust and auditable SOPs in place which reflect the principles of the increased governance arrangements. These SOPs are to set criteria (in terms of rank and qualifications) for individuals managing CD accounts and identify specific lines on the Operational Establishment Table (OET) where possible, stipulate the frequency of CD checks by both the account holder and the chain of command (including the requirement for formal handover/takeover checks), provide direction on the action to be taken when a discrepancy in the account is identified, and ascertain the means by which a pan theatre overview of the prescribing and supply of CDs is to be achieved. Issues relating to the management and use of CDs are to be communicated to PJHQ using the normal governance processes.

24. **Exercises**. Accountable officers are to ensure that units falling within their area of responsibility maintain management procedures for CDs on exercise and that a full audit trail remains in place in accordance with this policy.

Annexes:

A. Roles and Responsibilities of the CD Accountable Officer.
B. TORs for Subordinate Accountable Officers.
C. Quarterly Occurrence Report Template.
D. Annual Report Template.

ROLES AND RESPONSIBILITIES OF THE CD ACCOUNTABLE OFFICER

1. The Roles and Responsibilities of the MOD CD Accountable Officer (CDAO) have been developed from Regulation 11 of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 and are as follows:

a. **Safe Management and Use of CDs**. Establish, operate and review appropriate arrangements for the security, safe management and use of CDs by the designated body. In particular, the CDAO is to ensure that current policy and relevant legislation relating to CDs is complied with and that SOPs covering specific areas are in place.

b. **Ensure Adequate Destruction and Disposal Arrangements for CDs**. Ensure that existing policy and guidance for the disposal and destruction of CDs are complied with.

c. **Ensure Monitoring and Auditing of the Management and Use of CDs**. Establish and operate appropriate arrangements for monitoring and auditing the designated body's management and use of CDs. The arrangements must include monitoring and analysis of CD prescribing, including private prescriptions.

d. **Alert Systems**. The CDAO is to ensure that systems are in place:

(1) To allow timely response to any complaints/concerns involving CDs.

(2) For reporting untoward incidents involving CDs.

(3) For analysing and responding to these incidents.

e. **Ensure Relevant Individuals Receive Appropriate Training**. The CDAO is to ensure that arrangements are in place to provide appropriate training for any person carrying on an activity, including Reservists, involving the management and use of CDs (prescribing, supplying, administering or disposing of CDs). This includes receiving information and training on local SOPs and being updated when SOPs are reviewed or amended. This training requirement will need to be enabled through liaison with the single Service customer agents and JMC.

f. **Record, Assess, Investigate and Action Concerns Regarding Relevant Individuals**. The CDAO is to ensure that robust systems are in place to enable concerns to be raised and that appropriate arrangements for recording concerns about incidents that involve, or may have involved, improper management/use of CDs by specific individuals, are in place (see Annex C for further detail).

g. **Information Sharing**. The CDAO is to ensure that arrangements are in place to facilitate appropriate information sharing, disclosure and cooperation with other responsible bodies outside the MOD, regarding the management and use of CDs. This is particularly relevant for those organisations that employ personnel who have recently worked in, or continue to work across, several designated bodies and engagement with NHS Local Area Team Intelligence Networks (LINs) and NHS Trusts where Service Personnel are employed will be necessary[10].

[10] Further networking will be facilitated by participation in the CQC National and Cross Border meetings by SO1 Pharm.

h. **Occurrence Reports**. The CDAO is to generate an annual report for SG and IG detailing any trends and concerns that their designated body has regarding its management or use of controlled drugs or confirmation that the designated body has no concerns to report.

TERMS OF REFERENCE FOR SUBORDINATE ACCOUNTABLE OFFICERS

Description

1. The Subordinate Accountable Officers (SAO) is directly accountable to the Controlled Drug Accountable Officer (CDAO) and is to fulfil the AO role for locations within their Area of Responsibility (AOR) as described in this leaflet.

Qualities

2. The SAO must be a respected and suitably experienced person who does not routinely supply, administer or dispose of Controlled Drugs (CDs) or Accountable Drugs (ADs) as part of their duties. They should have credibility with all health and social care professionals and sufficient seniority (minimum OF4) to be able to take action regardless of how a concern is raised.

Duties

3. The SAO is to ensure that CDs and ADs are safely and responsibly managed at locations within their AOR. This includes:

a. Ensuring that adequate and up to date standard operating procedures (SOPs) are in place covering all activities concerning CDs and ADs.

b. Suitable training is in place for all individuals involved with the handling of CDs and ADs, including induction training and regular updates.

c. Adequate destruction and disposal arrangements are in place, including suitable access to witnesses iaw JSP 886.

d. Monitoring and audit arrangements are in place that scrutinise the management and use of CDs.

e. An effective system for reporting incidents and concerns is in place that is well publicised, accurately recorded and appropriately investigated.

f. Quarterly Occurrence Reports are completed and submitted to HQ SG within 4 weeks.

g. Information is actively and appropriately shared amongst available LINs.

Attestation of Understanding

4. The SAO is to read this policy leaflet at the start of their appointment. This should provide the SAO with a comprehensive understanding of their role that should be sufficient but more information can be obtained from SO1 Pharm, HQSG.

5. The SAO is to send a signed copy of this TOR to SO1 Pharm HQSG within one month of commencing their appointment, as evidence that they have reviewed this policy, understand the TORs and are confident that they can competently exercise their duties as an SAO.

Signed: **Name and Rank:**

Date: **Command:**

QUARTERLY OCCURRENCE REPORT

Name of Designated Body	Ministry of Defence
Command	
Subordinate Accountable Officer (SAO)	
Report for Period (Quarter)	

I confirm that the Command has **no / the following*** concerns regarding its management or use of controlled drugs during this period.

Number of Controlled Drug Significant Events raised this quarter:
* Delete as applicable

SAO Signature	
Date Signed	

Date SAO made aware	Description of Concern[11]	Actions Taken, Underway or Completed and Recommendations.

[11] Useful to identify what category the concern falls into: Fraud, theft, loss, patient related, any governance issues, training, individual or team and if there is a future risk. Also identify location (where possible), other agencies/organisations involved and type of MTF/unit.

Guidance Notes

1. This Occurrence Report is a template to be used by SAOs to provide a quarterly report of any concerns that their command has regarding the management and use of Controlled Drugs. Whilst concerns are usually highlighted as part of the usual governance framework, including the automated SE system, the SAO must also ensure that a process is in place to accommodate individual concerns that may arise outside this framework. As a minimum, the incident report must include:

a. The date on which the SAO was made aware of the concern.

b. Any dates on which the matters that led to the concern took place

c. The nature of the concern and the category (loss (theft, fraud, loss), patient related, governance, individual or team). Patient identifiable data is not to be included. Additional information can be supplied as a separate report if necessary.

d. Details of the relevant individual to whom the concern was expressed.

e. Details of the individual/body that raised the concern.

f. Details of any action taken, by whom and whether the incident is still open or closed.

g. An assessment as to whether any information should be disclosed to another responsible body; and if information was disclosed, the details that were disclosed including the name of the responsible body to whom it went and the nature of the information. The record may be kept in either electronic or paper format but access must be limited to the accountable officer (and staff) and any others who might reasonably require access to ensure the continued safe management or use of CDs.

ANNUAL REPORT TEMPLATE

Name of Designated Body	Ministry of Defence
Command	
Subordinate Accountable Officer (SAO)	
Annual Report for Period	
SAO Signature	
Date Signed	

Executive Summary

1. The purpose of this report is to assure the CDAO that the above Command manages CDs safely as an organisational priority.

Summary of Incidents

Categories	No of Occurrences	Comments
Losses: • Known theft • Known fraud • Unaccounted for losses	 Enter number of known theft Enter number of known fraud Enter number of losses	
Patient related incidents	Enter number of patient related incident	
Governance issues	Enter number of Governance issues	
Individuals of concern	Enter number of concerns relating to an individual	
Other	Enter number of all other incidents	

SOPs

2. SOPs for the management of CDs are / are not in place and were last updated on *{Enter date here}*. Use this paragraph to describe any ongoing work on SOPs/SOIs and where there are gaps.

Inspections

3. The following inspections have been undertaken during this reporting period:

   a. External.

b. Internal

Audits

4. Include a summary of any audits undertaken on the management and use of CDs.

Investigations

5. Include details on any complete or outstanding investigations, and a summary of actions taken to make systems safer and to minimise risks.

Unauthorised Destructions

6. Include any circumstances of unauthorised destructions or loss ie not witnessed or iaw JSP 886.

Attendance at Local Intelligence Networks

7. Include a summary of any attendance at LINs by MOD personnel.

Training

8. Include a summary of all training activities relating to the management of CDs.

Summary

9. Summary comments as required.

Signature block