Mountain Rescue Teams - Controlled Drugs Factsheet

Scope-

This factsheet has been prepared for all Mountain Rescue Team members, but especially those who can lawfully administer Controlled Drugs to casualties, either by virtue of their professional competence, or holding the requisite ‘Casualty (Cas) Care’ Certificate. Other Team Members may find this factsheet helpful to understand the importance of this function, and the responsibilities that lie with it.

It has been prepared in conjunction with the Home Office Drug Licensing, Medicines and Healthcare products Regulatory Agency (MHRA), the Mountain Rescue of England and Wales (MREW), and the Mountain Rescue Committee of Scotland (MRCoS). Without the co-operation of these agencies and organisations, possession of Controlled Drugs for use in rescue situations could not occur.

Legislation-

Certain drugs are ‘controlled’ under UK law on account of the potential harm they pose to people consuming them. These ‘Controlled Drugs’ are listed in the Misuse of Drugs Act 1971 (MDA 1971) and its associated Misuse of Drugs Regulations 2001 (MDR 2001).

Many of these drugs have recognised therapeutic benefits and are available to the public, in the form of a ‘medicinal product’ and, generally speaking, on prescription only. Controlled Drugs are subdivided into ‘Schedules’, on account of the ‘type’ of drug and potential for misuse/ harm. Drugs which may be used in Mountain Rescue settings include:

- Morphine (intravenous/ intramuscular), Diamorphine, Fentanyl- Schedule 2
- Midazolam- Schedule 3
- Diazepam, Ketamine- Schedule 4 (Part I)

The MDA 1971 sets out a number of ‘restrictions’ in respect of Controlled Drug use, and it provides for the operation of a Licensing regime to enable the lawful use of drugs in certain limited circumstances where authority in not already granted under regulations. This Licensing regime operates under the Misuse of Drugs Regulations 2001 and the Home Office are the Competent Authority for these purposes in Great Britain.

Where possession or use of a drug is prohibited by the MDA 1971, it can only be lawfully handled- by an individual or an organisation- when specifically authorised under the 2001 Regulations or in possession of a valid Home Office licence for that purpose (Schedule and activity specific- e.g. Schedule 2 possess and supply). To be unlawfully in possession of a controlled drug places the individual at risk of prosecution, with the possibility of a custodial sentence.
A handful of situations exist where certain drugs may be possessed in limited circumstances without a licence. One such example would be a Doctor (of Medicine), who can lawfully possess (without a HO licence) any drug in Schedules 2-4 of the MDR 2001 by virtue of their professional competence, for the purposes of administering to a patient. This ‘authority’ does not simply extend to any organisation for whom the Doctor works, whether that work is remunerated or voluntary.

So, for Mountain Rescue purposes, both MREW and MRCoS require licensing to lawfully possess controlled drugs, for the purposes of administration to casualties ‘in the field’, irrespective of whether a Doctor, or ‘Casualty Care’ Certificate holder administers them.

**A Home Office Licence may enable an organisation to lawfully possess certain schedules of drugs for certain purposes, but it provides no authority in itself to administer those drugs.**

For MREW and MRCoS, the administration provision for appropriately qualified team members is derived from two sources:

1. ‘Professional Competence’- for example GMC registered Doctors, HCPC Registered Paramedics- but to note that ‘administration ‘privileges’ of Controlled Drugs may be limited to certain schedules or individual drugs.

2. ‘Casualty Care’ Certificate holders- as defined in the Human Medicines Regulations 2012 (Regs 9 & 16) which provide for the administration by a ‘person ….holding a certificate of first aid….from the MREW …’ of any Prescription only Medicine (POM), Pharmacy Medicine (P) of General Sales List (GSL) Medicinal Products can be administered (supplied) ‘only as far is as necessary for the treatment of sick or injured persons in the course of providing mountain rescue services’.

In short, the ability to possess, supply and administer certain Controlled Drugs to sick or injured persons in the course of providing Mountain Rescue services exists because of the provisions afforded by two pieces of legislation. These are ‘owned’ by different government departments, who have worked in partnership with each other and the organisations concerned to enable MR teams to carry out their vital life saving work.

For avoidance of doubt, the Home Office and MHRA see their roles as enablers; we do not wish to prevent or prohibit either MREW or MRCoS undertaking their work. Licensing is a legal requirement, and it must be delivered in a robust yet proportionate fashion. Our role is not to determine clinical competence; it is to manage the inherent risks associated with Controlled Drugs, and their potential for abuse, misuse and diversion. In turn, licensees must satisfy us that they are competent, as individuals and ‘corporately’ that they are competent to hold a licence.

**Home Office Licensing-**

Holding a HO Controlled Drug license is an earned privilege, it is not a right, and can only be issued upon satisfactory completion of an application process and payment of the associated fee. All applications are subject to risk-assessed consideration, and premises can be visited by a Home Office Compliance Officer.

Licences are ordinarily issued to individual companies at individual premises (buildings), valid for a period of 12 months. Before the expiry of that licence, an application for a further licence must be made- renewal is not automatic.

In a handful of cases it is appropriate to consider issuing a ‘Licence Granting a Group Authority’. These are issued in exceptional cases only, for example where licensing on an individual site basis is impractical, the needs of a licensee are very specific and special conditions can be placed upon the licence, or use of drugs infrequent and in emergency situations.
MREW and MRCoS each hold Home Office Licences Granting a Group Authority to enable Teams affiliated to those organisations to possess and supply drugs in certain schedules for administration in critical Mountain Rescue situations.

This is a rare privilege; all Team Members should understand the significance of this. Their actions as individuals in respect of controlled drug handling could fundamentally affect the whole organisation’s ability to retain a licence, not just the Team to whom the individual belongs.

**Licensing conditions and your obligations**

Licensees have a number of obligations which they must comply with as conditions of their licence. These relate to various elements of the Controlled Drug handling process and every Team Member should be aware of and understand these obligations.

Failure to comply has consequences- ‘administrative sanctions or contraventions’ can be applied to a licence, which may mean more frequent licence visits, or shorter licence validity. Ultimately, where it is proportionate to do so, a licence can be revoked. This would severely curtail MRTs ability to deliver pain relief to casualties. Furthermore, if a weakness in process or poor execution of a sound process led to a drug being misappropriated, the implications could be serious. Potentially the drug may be abused by an individual or, in extreme circumstances, lead to an individual’s death within your community. This would have a reputational impact on the organisation concerned, and the regulatory authorities.

**A few general pointers:**

1. **Ordering of CDs**

   Should be undertaken only in accordance with professional competence and organisation protocol.

2. **Safe Storage of CDs**

   Drugs in certain Schedules must be stored in accordance with the Misuse of Drugs (Safe Custody) Regulations 1973. This determines how drugs should be stored in base safes, and, where storage on a vehicle is appropriate, in vehicle safes. In both cases safes must be bolted in place, and keys stored separately. You must familiarise yourself with the procedures in operation at your MRT, and the premise should be that CDs are securely locked away at all times, unless there is justification for doing otherwise- such as in a rescue deployment.

3. **Record Keeping**

   Robust record management is also a vital element of providing assurance to regulatory bodies that a licensee understands and effectively discharges the responsibilities bestowed upon them as a licensee.

   Record Keeping requirements are laid down in the Misuse of Drugs Regulations 2001. A clear and standardised way for keeping records provides the basis for audit of stock holdings, and it is easy to spot if anything is amiss. It can also help with drug management, for example if batch numbers and expiry dates are recorded, and ‘running balances’ must be used. This is important because, as a condition of the Authorities granted to MREW and MRCoS, stock holdings should
be kept at minimum operating levels; excessive stock must not build up. Individual teams should discuss ‘holdings’ with their Chief Medical Officer, we do not wish to be prescriptive in this regard.

**This book is effectively the ‘storybook’ for CD handling in your MRT.**

In short, the register needs to be a hard-bound book and record very clearly what you have, where it is, how/when/where it has been administered, losses/destructions and who has taken what action. Entries must be made in permanent ink, mistakes crossed through with a single line so the original entry is legible, and the new entry signed and dated - See MDR 2001.

Records of administration must be made; they are an inherent part of the records. It is accepted that the reality of ‘in the field’ administration cannot immediately be recorded in the CD register. Please ensure you do so as soon as possible, but when in the field, radio in details of administration if it is possible to do so. Recording the casualty name in the CD register may not accord with DPA principles, so a notation such as ‘CAS 1’ may be appropriate in the register, with the ‘identifier’ for CAS 1 being held securely elsewhere.

4. Changes to Opieate Responsible Servants/ Team Leaders

Changes in personnel or premises addresses need to be notified to the Chief Medical Officer, along with changes to holdings - e.g. a team choosing to hold CDs where they didn’t previously, or to not continue holding CDs. In turn, they will be passed to the Home Office. These details are recorded in Annexes to the licence and must be kept up to date.

5. Destruction- out of date stock

Any out of date CD containing medicines should be returned to the person from whom they were supplied for denaturing and destruction. For some drugs this must be witnessed. The appropriate entries should be made in the CD register to reflect those drugs are removed from team ‘stock’. In no circumstances should teams dispose of materials themselves.

5. Thefts and Losses

All thefts, losses or near misses should be reported to the Home Office and the Police- via your Team Leader and in turn to the Chief Medical Officer. We recognise the practical challenges posed by administering CDs in a ‘field’ environment and a consequential possibility for a loss there, though these are in practice extremely rate.

Detecting and reporting any adverse incidents is important; we need to work together to determine whether anything more could or should reasonably be done. Please do not withhold information- a learning point in one team may be a life-saver for another.

6. Annual Returns

Each organisation must submit an Annual Return of drug use and holdings by 31 January each year. This means Chief Medical Officers are reliant on the timely submission of your returns- please help them by completing accurate and timely returns when you are commissioned to do so. Failure to complete this could compromise the wider organisation’s ability to retain their licence so the importance of this task should not be underestimated.

The Home Office in turn must report Annual Statistics on Drug use to international bodies in Vienna.
Governance and the Chief Medical Officer's role-

The Chief Medical Officer is ultimately responsible for the Organisation's Controlled Drug governance. The significance of this position, and associated responsibility must not be underestimated. They have assumed this role for the ultimate benefit of the organisation and the public who may depend on the support you offer them in a critical incident. Their success, or failure, in this role is determined by the conduct and actions of Opiate Responsible Servants/ Medical Officers in each Team, and in turn by each Team Member. They depend on your support and professionalism to deliver first-class and life-saving Mountain Rescue Services. Please help them fulfil this role by understanding your responsibilities and the context for the licences held.

The operation of the Group Authorities depends on a significant element of consistency between Teams in the organisation. There are standards that need to be followed, as conditions of the licence, which have been outlined above. Within those ‘umbrellas’ how you deliver or comply with those standards may vary slightly between Teams. Any special conditions applied to the licence have been done so with a full understanding of your work, and on the principle of enabling Mountain Rescue activities, not seeking to prohibit or constrain beyond what is necessary to ensure regulatory compliance.

Published- 3 December 2014