



Royal Pharmaceutical Society Of Great Britain

Fitness to Practise and Legal Affairs Directorate Fact Sheet: Two

Controlled Drugs and Hospital Pharmacy

Introduction

This is an information sheet designed to be of assistance to pharmacists and others with like interests. The contents have not been issued as Council policy, but it is intended as a resource which pharmacists may use to review their practices and policies. It is not intended to interpret the law, the Code of Ethics or Council policies, but offers common sense guidance on issues of topical interest.

It should also be remembered that the enforcement body for all issues described in this fact sheet is the Home Office via the police. Additionally, The Royal Pharmaceutical Society has no enforcement jurisdiction in any area relating to hospital pharmacy, except where the pharmacy is also registered as a retail pharmacy business. For this reason pharmacists working within the NHS are also strongly advised to seek the advice, firstly of their hospital and/or trust management and legal advisers and also the Department of Health. In the case of private hospitals, pharmacists should consult guidance from the National Care Standards Commission (England), The Care Commission (Scotland) or Care Standards Inspectorate for Wales.

At the end of this fact sheet a list of Home Office Drugs Branch addresses and telephone numbers can be found. Contact numbers at the Department of Health and Care Standards regulatory bodies are also provided.

If any further queries should arise please do not hesitate to contact the Fitness to Practise and Legal Affairs Directorate on 020 7572 2308. Emails may be sent to ftp@rpsgb.org

1. Controlled Drugs in the Pharmacy

Sale and Supply

The hospital pharmacy will, under normal circumstances, supply controlled drugs in one of two ways.

1. In response to a requisition from a ward, theatre or other department in the hospital, for use as a stock item.

The Misuse of Drugs Regulations 2001 state in Regulation 14 (6), the following:

Where the person responsible for the dispensing and supply of medicines at any hospital or nursing home supplies a controlled drug to the sister or acting sister for the time being in charge of any ward, theatre, or other department in that hospital or nursing home (hereafter in this paragraph referred to as the recipient), he shall:-

- (a) obtain a requisition in writing, signed by the recipient, which specifies the total quantity of the drug to be supplied; and
- (b) mark the requisition in such manner as to show that it has been complied with,

and any requisition obtained for the purpose of this paragraph shall be retained in the dispensary at which the drug was supplied and a copy of the requisition or a note of it shall be retained by the recipient.

Although there have been calls for a change in the law, at the time of the writing of this document operating department assistants or operating department practitioners are not authorised to requisition Controlled Drugs.

Regulation 23 (3) of the Misuse of Drugs Regulations 2001 states that:

Every requisition, order or prescription (other than a health prescription) on which a controlled drug is supplied in pursuance of these Regulations shall be preserved for a period of two years from the date on which the last delivery under it was made.

2. In response to an inpatient prescription, an outpatient prescription, or a TTO. A request for a specific patient must comply with the prescription requirements laid down in Regulation 15 and discussed further in this fact sheet, unless the controlled drug is to be administered from ward stock (see section on Supply and Administration page 11).

2. The Supply of Controlled Drugs on Prescription

No prescription is required under The Regulations for the supply, by a pharmacist, of any Schedule 5 controlled drug but, for preparations above a certain strength, a prescription is required under the Medicines Act 1968. Prescriptions are necessary for all other categories of controlled drugs which are always prescription only medicines. The requirements of both the Misuse of Drugs Act and the Medicines Act must be satisfied.

It is an offence for a practitioner to issue a prescription for a Schedule 2 or 3 controlled drug, or for a pharmacist to dispense it, unless it complies with the following requirements;

- i. **It shall be in ink or otherwise be indelible and be signed by the person issuing it with his usual signature and dated by him.**

Notes: *Where a prescription is received which requires amending in any respect, the person who originally signed the prescription must amend it. An amendment by another doctor in the practice is not acceptable. If the prescribing doctor is not available, then the doctor on duty must issue a completely new prescription.*

Under no circumstances can prescription details be amended by a covering letter from the prescribing doctor purporting to give such authorisation.

Under no circumstances can a carbon copy or faxed prescription be accepted for a Schedule 2 or 3 controlled drug.

The doctor may either date the prescription in his own handwriting or use a rubber date stamp. However the Home Office are of the opinion that computer-generated dates are not acceptable.

- *Note that for phenobarbitone prescriptions handwriting requirements do not apply but prescription requirements do, meaning that a computer generated date would not be acceptable.*
- *Neither prescription nor handwriting requirements apply to prescriptions for temazepam preparations, hence a computer-generated date would be acceptable.*

The Regulations require the following information to be specified in the handwriting of the prescriber.

The Secretary of State has the power to waive the handwriting requirements either personally or as the member of a class. Confirmation of practitioners who have been granted such an exemption may be obtained from the Home Office directly on **020 7217 8230 or 020 7217 8713**. A practitioner with such an exemption is not required to hand write prescriptions for Schedule 2 and 3 controlled drugs and in some cases the prescription will actually be written by the doctors receptionist. This is acceptable so long as the prescribing doctor sees, signs and dates the prescription after it has been written and before it is issued.

Handwriting exemptions are usually only issued to doctors who prescribe for ten or more addicted patients. The Home Office does not consider it appropriate for a doctor to use his handwriting exemption for any other purpose such as the prescribing of CDs for treatment of injury or organic disease.

- ii. **Specify the address of the person issuing it.**

Notes: *The address of the prescriber must be within the United Kingdom (NB. the United Kingdom does not include the Channel Islands or the Isle of Man)*

It is acceptable for the prescription to be stamped by one doctor and signed by a different prescribing doctor so long as the addresses are the same.

iii. Have written thereon, if issued by a dentist, the words “for dental treatment only”.

Any requests for controlled drugs for which no recognised dental use exists should be challenged. In cases of difficulty the Home Office or the General Dental Council (Telephone No: 020 7486 2171) should be contacted.

iv. Prescriptions issued by a veterinary practitioner must contain a declaration that the controlled drug is prescribed for the treatment of an animal or herd under my care.

v. The name and address of the patient or, for veterinary prescriptions, the name and address of the person to whom the controlled drug prescribed is to be delivered.

In some cases, a patient will not have "an address". It is generally acceptable that in those circumstances "No fixed abode" would comply with the requirements.

vi. Specify the dose to be taken.

Notes: *The Home Office opinion is that a dose of to be taken as directed or to be taken when required is not acceptable however, a dosage of one to be taken as directed/when required is acceptable.*

Prescriptions for controlled drugs to be used in a syringe driver must specify the number of ampoules or the amount of controlled drug to be used over a specified period of time, for example “Four ampoules to be used in a syringe driver as directed” would be acceptable

vii. Specify the form of the preparation.

Notes: *Where a controlled drug in the form of a preparation is requested the form must be stated on the prescription even where only one form exists or where the form is implicit in the proprietary name, e.g. MST Continus tablets.*

*The Fitness to Practise and Legal Affairs Directorate is of the opinion that the abbreviation **t** or **c** as an expression of form is not acceptable whereas **tabs** or **caps** is acceptable.*

viii. Where appropriate, the strength of the preparation.

Notes: *Where more than one strength is available then the strength must be specified on the prescription, although it does not legally need to be expressed in words and figures.*

If a prescriber orders a strength of controlled drug which does not exist, the prescription must be amended to specify the total quantity of controlled drug in terms of the available strengths, e.g.

MST Continus tablets 50 (fifty) x 10mg tablets and MST Continus tablets 50 (fifty) x 30mg tablets

- ix. **Either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units to be supplied;**

In any other case, the total quantity (in both words and figures) of the controlled drug to be supplied.

Notes: *The Home Office are of the opinion that where a controlled drug is available as a dosage unit, the total quantity on a prescription should be expressed in terms of the number of dosage units, e.g. for tablets, capsules, suppositories 10 (ten) would be acceptable.*

*An expression of the total quantity in terms of the total quantity of controlled drug, where a dosage unit exists, would not be acceptable and can lead to ambiguity, e.g., **MST Continus tablets 10mg x 10 (100 mg) one hundred milligrams** is unacceptable. The quantity must be expressed as **MST Continus tablets 10mg 10 (ten) tablets**.*

The total quantity of a controlled drug which is not available in the form of a preparation, can be expressed in terms of the actual amount of controlled drug, e.g. Cocaine powder 2g (two grammes).

The use of abbreviations such as ml is acceptable so long as the prescription remains unambiguous and the prescriber's intention is clear.

These prescription requirements may at first sight appear to be very precise and unnecessarily restrictive but they are designed to protect both the prescriber and the supplying pharmacist. Any ambiguities on a controlled drugs prescription should be clarified with the prescriber and the appropriate amendments made prior to supply. Each time a CD is supplied, the date of supply must be marked on the prescription.

It is an offence under the Act for a pharmacist to supply a controlled drug before, or later than thirteen weeks after, the date specified on the prescription.

Under no circumstances is it acceptable for a hospital pharmacy to accept a facsimile prescription to facilitate the supply of discharge medication consisting of a controlled drug, unless the original prescription will be received and checked in the pharmacy before the medication is supplied to the patient.

Temazepam Prescriptions

Prescriptions for temazepam preparations are exempted from all the prescription and handwriting requirements of the Regulations. As previously mentioned this means that computer generated dates are acceptable and the prescription does not need to be in the handwriting of the prescriber. Notwithstanding these relaxations, any prescription for temazepam is only valid for thirteen weeks from the date specified by the prescriber thereon. Under no circumstances, be it on a NHS or private prescription, are repeats allowed for temazepam prescriptions. It is still a statutory requirement for the pharmacist not to make a supply of any controlled drug other than one specified in Schedule 4 or 5, unless he is either acquainted with the signature of the person by whom it purports to be issued and has no reason to suppose that it is not genuine, or has taken reasonably sufficient steps to satisfy himself that it is genuine.

Prescriptions for Fentanyl Patches

The strength on a Controlled Drugs prescription should always be unambiguously expressed so as to identify clearly which preparation is being requested. Confusion often arises where expressions such as Fentanyl 25 Patches are stated on prescriptions, where the figure of 25 actually represents the release rate per hour of the preparation, each patch containing a total of 2.5mg of fentanyl.

Notwithstanding this there can be no doubt as to which strength is being ordered on such a prescription and an expression of strength of this nature is acceptable.

The dosage should be expressed in terms of the interval between patch application, for example, one patch to be applied every 72 hours.

Before discussing issues of the possession, supply and administration on wards, it is proposed to address other issues concerning controlled drugs which pharmacists may encounter in hospital pharmacy.

Safe Custody

There are no provisions within The Misuse of Drugs (Safe Custody) Regulations 1973 that are applicable to the storage of controlled drugs in NHS hospitals. Hence the stringent requirements relating to safes and cabinets stipulated in the Regulations do not apply to the receptacles used to store controlled drugs in hospital pharmacies (except those which are registered with the Society as 'registered retail pharmacies').

The Regulations require that a controlled drug should in any event, be kept in a 'locked receptacle' which can only be opened by a person who can lawfully be in possession of the drugs, for example a pharmacist, or person authorised by him. The specification of that locked receptacle is not laid down in legislation.

It is suggested that senior management within the hospital undertake risk assessments to determine the level of security needed (e.g large volumes of dilute controlled drug preparations may require less security than ampoules containing raw or pure controlled drugs).

Private hospitals, which operate under the terms of a Home Office licence, should ensure safe custody arrangements correspond with any terms in the licence. Guidance may also be available from National Care Standards Commission (England), The Care Commission (Scotland) or the Care Standards Inspectorate for Wales.

Record Keeping

Records must be kept by the pharmacy of all Schedule 1 and 2 Controlled Drugs received or supplied.

The following particulars are to be recorded for Controlled Drugs received:

- (a) date on which received;
- (b) name and address of person or firm from whom received;
- (c) amount received;
- (d) form in which received.

For Controlled Drugs supplied the following must be recorded:

- (a) date on which the supply was made;
- (b) name and address of person or firm to whom supplied;

- (c) particulars as to licence or authority of the person or firm supplied to be in possession of Controlled Drugs;
- (d) amount supplied;
- (e) form in which supplied.

The following points are important in relation to the keeping of Controlled Drug registers.

- a) Entries must be in chronological sequence.
- b) A separate part of the register must be used for each class of drugs. Separate sections are required for amphetamines (which includes dexamphetamine) and methylamphetamine.
- c) If desired, separate parts of the register can be used for different drugs or strengths of drugs comprised within a class of drugs.
- d) The class of drugs must be specified at the head of each page.
- e) Entries must be made on the day of the transaction or on the next day following.
- f) No cancellation, obliteration or alteration may be made; correction must be by dated marginal note or footnote.
- g) Entries must be in ink or otherwise indelible.
- h) The register must not be used for other purposes.
- i) The register must be kept at the premises to which it is related and a separate register must be kept for each premises of the business.
- j) With Home Office approval, separate registers may be kept for each department of a business.
- k) Particulars of stocks receipts and supplies must be furnished to any authorised person on request (this includes inspectors of the Royal Pharmaceutical Society and police chemist liaison officers). Other documents and stocks of drugs must also be produced if required.
- l) Registers must be kept for two years from the last date of entry.

No entry need be made in the prescription-only register under the Medicines Act 1968, but it is good practice to make such entries in circumstances where such records would otherwise be kept for the CD by virtue of its status as a POM e.g. Private prescriptions.

Destruction of Controlled Drugs in the Hospital Pharmacy

Any person required by The Regulations to keep records of Controlled Drugs, that is Schedule 1 and 2 drugs, may only destroy them in the presence of a person authorised by the Secretary of State either personally or as a member of a class. The latter includes Inspectors of the Royal Pharmaceutical Society of Great Britain, police chemist liaison officers and Home Office Inspectors. Pharmaceutical Society Inspectors only witness the destruction of controlled drugs in registered retail pharmacy premises. Hospital pharmacists often enquire as to whom is authorised in their hospital to witness such destruction. In addition to those already mentioned, there will sometimes be a member of the Hospital Administration or Trust Executive who can be authorised and pharmacists are advised to check with their local Home Office Drugs Branch in this regard. A pharmacist or practitioner may destroy Controlled Drugs returned to him by a patient or patient's representative without the presence of an authorised witness. Such controlled drugs should not be returned to stock.

As the quantity of Controlled Drugs returned can often pose a storage problem, as well as an increased security risk, pharmacists are encouraged to destroy any patient returned controlled drugs as soon as possible. It is good practice to record the returned stock and the date of its destruction in a record book other than the controlled drugs register or on separate record sheets. This policy is strongly recommended and the form of these records left to the individual discretion of the pharmacist.

Within private hospitals and care homes, the procedures for the destruction of CDs may be dictated by the CD licences and checks should be made with the Home Office.

Requisitions for Schedules 1, 2 and 3 Controlled Drugs

A requisition in writing must be obtained by a supplier before he delivers any Controlled Drug (except those in Schedules 4 and 5) to any of the following:

- a. a practitioner;
- b. the matron or acting matron of a hospital or nursing home (a requisition from the matron of a hospital or nursing home must be countersigned by a doctor or dentist employed or engaged there);
- c. a sister or acting sister for the time being in charge of any ward, theatre or other department of a hospital or nursing home who obtains a supply of a Controlled Drug from the person responsible for dispensing and supplying medicines at that hospital or nursing home must furnish a requisition in writing signed by her which specifies the total quantity of the drug required. She must retain a copy or note of the requisition. The person responsible for the dispensing and supply of the Controlled Drug must mark the requisition in such a manner as to show that it has been complied with and must retain the requisition in the dispensary (currently, operating department assistants or operating department practitioners are not authorised to requisition Controlled Drugs);
- d. a person who is in charge of a laboratory the recognised activities of which consist in or include the conduct of scientific education or research;
- e. the owner of a ship or the master of a ship which does not carry a doctor on board as part of her complement;
- f. the installation manager of an offshore installation;
- g. the master of a foreign ship in a port in Great Britain (a requisition from the master of a foreign ship must contain a statement from the local medical officer of health that the quantity of drug is necessary for the equipment of the ship).

The requisition must be signed by the "recipient," state his name, address and profession or occupation, and specify the total quantity of the drug and the purpose for which it is required. The supplier must be reasonably satisfied that the signature is that of the person purporting to sign the requisition and that he is engaged in the occupation stated.

A messenger sent by a purchaser ("recipient") to collect a Controlled Drug on his behalf may only be supplied with the Controlled Drug if he produces to the supplier a statement in writing given by the recipient to the effect that the messenger is empowered to receive the drug on his behalf. The supplier must be reasonably satisfied that the document is genuine and must retain it for two years. This does not apply to a person carrying on a business as a carrier engaged by the supplier. A requisition must be retained for two years from the date of the last delivery made under it.

Care Homes

If the hospital pharmacy has a wholesale dealer's licence, or is registered with the Society as a registered retail pharmacy, the pharmacist may supply Schedule 2 and 3 controlled drug stock items to:

The person in charge or acting person in charge of a hospital or care home (formerly a nursing home) which is wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions.

This means that private hospitals, private care homes (formerly nursing homes) and private hospices may only hold stocks of Schedule 2 and 3 Controlled Drugs in accordance with the terms of a Home Office Licence.

The pharmacist must ensure that the home requesting the supply has the requisite licence before making the supply of any Schedule 2 or 3 Controlled Drugs. A requisition must also be obtained. A requisition supplied by a person (or acting person) in charge of a hospital or care home must be signed by a doctor or dentist who is employed or engaged there and the requisition must comply with the legislative requirements discussed earlier.

Under no circumstances can an order for a Schedule 2 or 3 Controlled Drug be accepted over the telephone or by any other verbal method.

3. Controlled Drugs on the Ward

Once the controlled drugs, which have been requisitioned from the pharmacy in the manner described in the previous section, reach the ward, theatre or other department of destination they become the ultimate responsibility of the sister, or acting sister for the time being in charge of that ward theatre or other department. It is sometimes the case that the key holding for the controlled drug cabinet is delegated to another by the sister or acting sister for the purpose of ease of access. It still remains the case that the ultimate responsibility rests with the sister or acting sister and any delegation of access to controlled drugs in this manner needs to be confirmed with the Hospital and Trust advisors and insurers.

Supply and Administration

The Misuse of Drugs Regulations 2001 state that a sister or acting sister for the time being in charge of a ward, theatre, or other department, may not supply any drug otherwise than for administration to a patient in the ward, theatre or department in accordance with the directions of a doctor or dentist. The sister or acting sister cannot delegate the supply function to any other person.

The Regulations also allow the prescription for the treatment of a patient in a hospital or nursing home to be written on the patients bed card or case sheet. What form these directions need to take remains unclear. If the transaction is the *supply* of a controlled drug then the prescription requirements in their entirety would need to be satisfied, as previously discussed. If on the other hand the transaction is to be regarded as the *administration* of a controlled drug from ward stock then the directions would not need to satisfy the prescription requirements. The legality of verbal directions to administer controlled drugs on the ward depends very much on which category this transaction falls into, but anything less than written instructions to administer a controlled drug should be rejected, for the protection of both the patient and the nurse. This question remains to be judicially determined and pharmacists are advised to check with the Trust legal advisers before adopting such a procedure involving any verbal directions.

There is no *statutory* requirement for the administration of controlled drugs on the ward to be witnessed by somebody although this may very often be the practice of a particular Hospital or Trust, following Department of Health guidelines. Private hospitals should ensure that any

guidelines on administration issued by the National Care Standards Commission (England), The Care Commission (Scotland) or the Care Standards Inspectorate for Wales are adhered to.

Record Keeping

The sister or acting sister for the time being in charge of a ward theatre or other department is not required by the Misuse of Drugs Regulations 2001 to keep any register. However, Department of Health guidance should be followed. It follows that ward stocks of controlled drugs may be destroyed without the attendance of an authorised person and indeed this is more desirable than returning to the pharmacy for the purpose of destruction. Pharmacists should be involved in the preparation of any procedures for destroying stocks of controlled drugs on the ward.

Possession of Illegal Substances

On occasion pharmacists will be asked to deal with substances removed from patients on admission to hospital which may include Schedule 1 controlled drugs, for example, cannabis. As a licence is required to possess Schedule 1 controlled drugs, the pharmacist cannot take possession of the product other than in two cases where exemptions are granted.

1. Where a person takes possession of a controlled drug for the purpose of destruction, and
2. For the purpose of handing over to a police officer.

The patient's confidentiality should normally be maintained, and the police should be called in only on the understanding that there will be no identification of the source. However, if the quantity is so large that the drug could not be purely for personal use, the pharmacist may decide that the greater interest of the public requires identification of the source. Such a decision should not be taken without first discussing with other health professionals involved in the patient's care, and the hospital's legal adviser and if possible the Department of Health.

In theory the patient should give authority for the removal and destruction of the drug. If the patient refuses, then the hospital may feel that it has no alternative other than to call in the police. **Under no circumstances can a Schedule 1 controlled drug be handed back to a patient on discharge, as the person doing so could be guilty of an offence of the unlawful supply of a controlled drug.** The penalties for this type of offence are high and often result in a custodial sentence.

Safe Custody

As discussed earlier in relation to controlled drug storage in the hospital pharmacy, the very stringent provisions of The Misuse of Drugs (Safe Custody) Regulations 1973 do not have any application to the safe custody of controlled drugs in wards, theatres or other departments of NHS hospitals. The only requirement is that the controlled drugs must be kept in a locked receptacle that can only be opened by a person who can lawfully be in possession (e.g. sister or acting sister) or somebody acting on their behalf.

As before, specifications for any locked receptacle used for the storage of controlled drugs in wards are not laid down in legislation or official guidance. Therefore, it is the responsibility of hospital senior management to undertake the necessary risk assessments to determine the level of security required.

Private hospitals, which operate under the terms of a Home Office licence, should ensure safe custody arrangements correspond with any terms in the licence. Guidance may also be

available from the National Care Standards Commission (England), The Care Commission (Scotland) or the Care Standards Inspectorate for Wales.

Patients Travelling Abroad

Prescribed drugs listed in Schedules 4 Part II (CD Anab) [only when in the form of a medicinal product and for administration by a person to himself] and 5 of the Misuse of Drugs Regulations 2001 are not subject to import or export licensing. However, some countries, do not allow patients to possess Controlled Drugs in these Schedules. Pharmacists should advise patients to check with the relevant embassy before travel.

Pharmacists are advised that patients intending to carry Schedule 2, 3 and 4 Part I (CD Benz) and Part II (CD Anab) drugs abroad may require an export licence (subject to the above exemption for Sch 4 Part II). This is dependent upon the amount of the drug to be exported.

There is no standard application form but applications should be supported by a letter from the prescribing doctor detailing:

- the name and address of the patient
- the name, form and strength of the preparation
- the total quantity to be taken out of the country
- the dates of departure from and return to the UK and the country of destination.

Applications and requests for further information should be sent to:

The Home Office Drugs Branch,
Room 354,
Horseferry House,
Dean Ryle Street,
London,
SW1P 2AW

Further details on export licences can be found in the BNF under the Section on Controlled Drugs and Drug Dependence.

Appendix One

Home Office Drugs Branch Contact Numbers

Regional Offices

South Eastern Region Inspectors

Room 354,
Horseferry House,
Dean Ryle Street,
London,
SW1P 2AW

Tel: 020 7217 8397

Midland Region Inspectors

PO BOX 26
Bristol,
BS99 7HQ

Tel: 0117 927 6736

Northern Region

Jefferson House
27 Park Place
LEEDS
LS1 2SZ

Tel: 0113 220 4570

Policy Queries: 020 7273 4131

Licensing Queries: 020 7217 0615

Export Queries: 020 7217 8457

Handwriting Exemptions: 020 7217 8230 or 020 7217 8713

Appendix Two

Department of Health Contact Numbers

The Department of Health
Pharmaceutical Division
Richmond House
79 Whitehall
LONDON
SW1A 2NS

(Tel: 020 7210 5532)

Appendix Three

Care Standards Contact Numbers

England

National Care Standards Commission

St Nicholas Building
St Nicholas Street
Newcastle Upon Tyne
Email: enquiries@ncsc.gov.uk

(Tel: 0191 233 3600)

Scotland

The Care Commission

Compass House
11 Riverside Drive
Dundee
DD1 4NY

(Tel: 01382 207100)

Wales

Care Standards Inspectorate for Wales

National Office
Units 4-5 Charnwood Court
Heol Billingsley
Parc Nantgarw
Nantgarw
Near Cardiff
CF15 7QZ

(Tel: 01443 848450)