



Royal Pharmaceutical Society Of Great Britain

Fitness to Practise and Legal Affairs Directorate Fact Sheet: One

Controlled Drugs and Community Pharmacy

Introduction

This is an information sheet designed to be of assistance to pharmacists and registered pharmacy technicians. The contents have not been issued as Council policy, but it is intended as a resource which pharmacists and registered pharmacy technicians 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 on all issues described in this fact sheet is the Home Office via the police. However, if any questions arise from this document, please do not hesitate to contact the Fitness to Practise and Legal Affairs Directorate on 020-7572-2308 for further clarification. Email queries may be sent to ftp@rpsgb.org. A section on controlled drugs on the Society's website contains some frequently asked questions, which can be accessed at: www.rpsgb.org/worldofpharmacy/useofmedicines/controlleddrugs.html.

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1. Classification of Controlled Drugs

The Misuse of Drugs Regulations 2001, as amended, classify controlled drugs into five Schedules according to the different levels of control attributed to each. It is those classifications which are described in the following paragraphs.

Schedule 1 drugs (CD Lic POM)

Schedule 1 includes the hallucinogenic drugs (for example LSD) and ecstasy-type substances, which have virtually no therapeutic use. Production, possession and supply of drugs in this Schedule are limited, in the public interest, for the purposes of research or other special purposes. A licence from the Home Office is needed for any of these purposes, and, apart from licence holders, the class of persons who may lawfully possess them is very limited. It does not include practitioners and pharmacists except under licence.

Some pharmacists may be asked to deal with controlled drugs returned by patients, which may be Schedule 1 products (for example cannabis). As a licence is required to possess Schedule 1 products, the pharmacist cannot take possession of the product other than in the two cases where exemptions are granted. The first exemption, is where a person takes possession of a controlled drug for the purpose of destruction, and the second, 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 on the understanding that there will be no identification of the source. If, however, the quantity is so large that the drug could not be purely for personal use, the pharmacist may decide that the greater interests of the public require identification of the source. Such a decision should not be taken without first considering discussing with the other health professionals involved in the patient's care, and taking advice from the pharmacist's professional indemnity insurance provider's legal adviser.

Under no circumstances can a Schedule 1 drug be handed back to a patient, as the person doing so could be guilty of an offence of unlawful supply of a controlled drug. The penalties for this type of offence are high, and often involve a custodial sentence.

Schedule 2 drugs (CD POM)

Schedule 2 includes the opiates (such as diamorphine, morphine and methadone), the major stimulants (such as the amphetamines) and quinalbarbitone. A licence is needed to import or export drugs in this Schedule, but they may be manufactured or compounded by a licence holder, a practitioner, a pharmacist, or a person lawfully conducting a retail pharmacy business acting in his capacity as such.

A pharmacist may supply them to a patient, only on the authority of a prescription in the required form (see Section 5 – *The Supply of Controlled Drugs on Prescription*) issued by an appropriate practitioner. The drugs may be administered to a patient by a doctor, dentist, nurse independent prescriber, acting in their own right, or by a supplementary prescriber (acting in accordance with a clinical management plan) or by any person acting in accordance with the directions of these healthcare professionals. At present, pharmacist independent prescribers cannot prescribe controlled drugs, administer them in their own right or direct their administration.

Requirements as to safe custody in pharmacies apply to all Schedule 2 controlled drugs except quinalbarbitone. Control over destruction applies to all Schedule 2 controlled drugs, and the provisions relating to the marking of containers and the keeping of records must also be observed (see Section 5 – *The Supply of Controlled Drugs on Prescription*).

Schedule 3 drugs (CD No Register POM)

Schedule 3 includes a small number of minor stimulant drugs such as benzphetamine, and other drugs which are not thought so likely to be misused as the drugs in Schedule 2, nor to be so harmful if misused.

The controls which apply to Schedule 2 also apply to drugs in this Schedule, except:

- (a) there is a difference in the classes of persons who may possess and supply them;
- (b) the requirements for an authorised witness to attend during destruction (of date expired stock) does not apply in retail pharmacy;
- (c) records in the controlled drugs register need not be kept in respect of these drugs;
- (d) safe custody requirements do not apply, **except** to preparations of diethylpropion, buprenorphine, temazepam and flunitrazepam. The requirement for safe custody of these particular Schedule 3 drugs also applies to those which are returned by patients, until such time as they are denatured for disposal. Any drugs added to Schedule 3 require safe custody unless specifically exempted. When midazolam is reclassified from Schedule 4 Part I to Schedule 3 on the 1st January 2008, it will be exempt from the requirement for safe custody.

Invoices for Schedule 3 controlled drugs must be kept, by retail dealers, for two years.

Schedule 4 drugs (CD Benz POM and CD Anab POM)

Schedule 4 is split into two parts:

Part I (CD Benz POM) contains most of the benzodiazepines and ketamine.

Part II (CD Anab POM) contains most of the anabolic and androgenic steroids, together with clenbuterol (adrenoceptor stimulant) and growth hormones (5 polypeptide hormones).

The same restrictions applicable to Schedule 3 drugs apply to Schedule 4 controlled drugs with the following relaxations:

- (a) Part I (CD Benz POM) are subject to full import, export and possession controls. An Home Office import or export licence is required for the importation and exportation of substances in Part II (CD Anab POM) of Schedule 4 **unless the substance is in the form of a medicinal product and is for administration by a person to them self.** There is no restriction on the possession of any Schedule 4 Part II (CD Anab POM) drug when contained in a medicinal product;
- (b) labelling requirements do not apply, except those contained in the Medicines Act 1968;
- (c) prescription requirements under the Misuse of Drugs Regulations 2001, as amended, do not apply, except for the validity of a prescription being limited to 28 days; however prescription requirements falling under the controls of the Medicines Act 1968 continue to apply;
- (d) records in the controlled drug register need not be kept by retailers;
- (e) destruction requirements apply only to importers, exporters and manufacturers;
- (f) there are no safe custody requirements.

Schedule 5 drugs (CD Inv POM or CD Inv P)

Schedule 5 contains preparations of certain controlled drugs, for example, codeine, pholcodine and morphine, which are exempt from full control when present in medicinal products of low strength as specified in Schedule 5. There is no restriction on the import, export, possession or administration of these preparations, and safe custody requirements do not apply. A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any of them.

No record in the controlled drug register needs to be made in respect of Schedule 5 drugs obtained or supplied by a person lawfully conducting a retail pharmacy business.

A preparation containing a Schedule 5 controlled drug without a Marketing Authorisation, (for example extemporaneously prepared products), would be classed as a prescription only medicine. Only Schedule 5 drugs contained in products of extremely high dilution (one part in a million (6x) or one part in a million million (6c)) in certain circumstances are exempt from prescription only status. A manufacturer of a product containing a Schedule 5 controlled drug could apply to the Medicines and Healthcare products Regulatory Agency (MHRA) for a product to be licensed as a Pharmacy (P) medicine or General Sale List (GSL) medicine.

The use of any Schedule 2 drug used in the preparation of a Schedule 5 medicinal product, must be recorded in the controlled drug register so as to account for the reduction in stock of the Schedule 2 drug.

No authority is required to destroy Schedule 5 controlled drugs, and there are no special labelling requirements (however, the Medicines Act 1968 labelling requirements still apply).

Invoices for Schedule 5 controlled drugs must be kept for two years.

2. Possession and Supply of Controlled Drugs

It is unlawful for any person to be in possession of controlled drugs other than those in Schedule 5, unless:

- (a) that person holds an appropriate licence from the Home Office;
- (b) that person is one of the persons specified in the Misuse of Drugs Regulations 2001, as amended;
- (c) the Regulations provide that possession of that drug or group of drugs is not unlawful, for example there is no restriction on the possession of any Schedule 4 Part II (CD Anab POM) drug when contained in a medicinal product; or
- (d) they have been lawfully prescribed for that person, (or for that person's animal).

In any case, possession or supply is not lawful unless the person concerned is acting in his capacity as a member of his class, or in accordance with the terms of his licence or group authority.

Practitioners and pharmacists are amongst those who have a general authority to possess, supply and procure all controlled drugs, except those in Schedule 1.

Certain other persons, including wholesaler dealers, importers and exporters, must obtain licences from the Secretary of State. "Wholesale dealer" in this context, means a person who carries on the business of selling drugs to persons who buy to sell or supply again.

Any person who is lawfully in possession of a controlled drug may supply that drug to the person from whom he lawfully obtained it. However, other legislation, such as the Hazardous Waste (England and Wales) Regulations 2005, may prevent controlled drugs being returned to a community pharmacy, (for further information see Section 16 – *Destruction of Controlled Drugs*).

3. Requisitions for Controlled Drugs

Requisitions for Schedule 1, 2 and 3 Controlled Drugs

A requisition in writing must be obtained by a supplier before delivering any controlled drug (except those in Schedules 4 and 5) to any of the following:

- (a) practitioner;
- (b) a person in charge or acting person in charge of a hospital or care home (which would formerly have been designated a nursing home). A requisition from the person in charge or acting person in charge of a hospital or care home (which would formerly have been designated a nursing home) must be countersigned by a doctor or dentist employed or engaged there;
- (c) a senior registered nurse or acting senior registered nurse for the time being in charge of any ward, theatre or other department of a hospital or nursing home, (hereafter known as "the senior registered nurse"), 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 "the senior registered nurse", which specifies the total quantity of the drug required. "The senior registered nurse" 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.
- (d) a person who is in charge of a laboratory, the recognised activities of which consist of 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 the ship's 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 proper officer of the port health authority, or, in Scotland, the medical officer designated under section 14 of the National Health Service (Scotland) Act 1978 by the Health Board, within whose jurisdiction the ship is, that the quantity of drug to be supplied is necessary for the equipment of the ship);
- (h) a supplementary prescriber.

The requisition must:

- be signed by the recipient;
- state the recipient's name, address and profession or occupation;
- specify the total quantity of the drug;
- specify the purpose for which it is required; and
- be in writing, however, it does not have to be in the practitioner's (or other authorised person's) own handwriting.

The supplier must be reasonably satisfied that the signature is that of the person purporting to sign the requisition and that, that person is engaged in the occupation stated.

A faxed requisition for a controlled drug is not acceptable.

Only whole packs can be supplied in wholesale transactions of this nature.

Messengers sent by a purchaser (recipient) to collect a controlled drug on their behalf may only be supplied with the controlled drug if they produce to the supplier, a statement in writing, given by the recipient, to the effect that the messenger is empowered to receive the drug on their 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.

Currently requisitions (signed orders) do not have to be written on any specific or standard form, although this may change in the future. Until 1st January 2008 all requisitions must be retained for two years from the date of the last delivery made under it. Whether this will continue to be the case after 1st January 2008 will depend on whether the appropriate changes are made to the Medicines (Sale or Supply)(Miscellaneous Provisions) Regulations 1980, as amended.

Again, subject to there being the appropriate changes made to the Medicines (Sale or Supply)(Miscellaneous Provisions) Regulations 1980, as amended, from 1st January 2008, requisitions against which supplies are made by pharmacists in a community setting (not a care home or a hospital) must be sent to the relevant National Health Service agency in accordance with arrangements specified by that agency. This requirement does not apply to requisitions written by veterinary practitioners or veterinary surgeons.

From 1st January 2008, the supplier of a Schedule 1, 2 or 3 controlled drug against a requisition must:

- (i) on receipt, mark on the requisition (in ink or otherwise indelibly) the supplier's name and address;

***Note:** The Home Office has confirmed that a pharmacy stamp can be used to mark these details on the requisition. Where a pharmacy stamp is used to mark the supplier's details on the requisition, the Home Office has expressed the view that the impression left by the stamp must be clear and legible. If stamps are used that do not produce legible details, the Home Office may alter its view on the acceptability of using a pharmacy stamp for this purpose.*

- (ii) send the requisition to the relevant National Health Service agency in accordance with arrangements specified by that agency, (subject to further changes in legislation occurring).

The above requirements numbered (i) and (ii) concerning requisitions will not apply:

- (a) where the pharmacist is a person responsible for the dispensing and supply of medicines at a care home, (or hospital);
- (b) where the requisition is a “veterinary requisition”. A “veterinary requisition” is a requisition which states that the recipient is a veterinary surgeon or veterinary practitioner. The requirements for a requisition, as described above, state that the requisition must specify “the recipient’s profession or occupation”.

In Scotland:

A GP10A(stock order) form is used by doctors in Scotland for obtaining stock, including controlled drugs, for practice use in their surgeries. The form does not have to be completed in the doctor’s handwriting, (but must be signed by the doctor).

In addition, a separate signed order would still be required. (In practice, a duplicate could be supplied by the doctor, as this form satisfies all the requirements for a signed order.) The GP10A(stock order) form can no longer be photocopied (and then signed) due to the introduction of additional security measures.

Supply of a Schedule 2 or 3 controlled drug for stock to a practitioner in an emergency:

Where a practitioner represents that a Schedule 2 or 3 controlled drug is urgently required for the purpose of the practitioner’s profession, the supplier may, if reasonably satisfied that the practitioner so requires the drug and is, by reason of some emergency, unable to furnish the supplier with a requisition in writing duly signed, deliver the drug to the practitioner on an undertaking by that practitioner to furnish such a requisition within the next 24 hours following. Failure to furnish the requisition within 24 hours, is an offence on the part of the practitioner.

Pharmacists should note that this provision is only to be utilised in situations of genuine emergency and it should be remembered that the circumstances in which a practitioner would be unable to deliver a requisition due to the nature of the emergency will be very limited. The provision is intended to allow a doctor, dentist or veterinary practitioner to call at the pharmacy and request a controlled drug without furnishing the pharmacist with a requisition. It does not permit a supply to any other person.

4. Safe Custody of Controlled Drugs

The Regulations relating to safe custody apply to all controlled drugs included in Schedules 1 and 2 (except quinalbarbitone), plus diethylpropion, temazepam, buprenorphine and flunitrazepam, which are Schedule 3 controlled drugs. Any new additions to the list of controlled drugs in Schedule 3 will require safe custody unless specifically exempted.

Although quinalbarbitone is not subject to the safe custody requirements, pharmacists may wish to keep the drug in the controlled drug cupboard to serve as a reminder that an entry is required in the controlled drug register.

Phenobarbital (Phenobarbitone), (a 5, 5 disubstituted barbituric acid), does not legally require safe custody.

From 1st January 2008, midazolam will be re-classified as a Schedule 3 controlled drug, (from its current status as a Schedule 4 Part I controlled drug). When it is re-classified, Midazolam will be exempt from the requirements relating to safe custody.

Retail dealers, (and care homes), must comply with the requirements for safe custody where they apply and must ensure that the relevant controlled drugs are kept in a locked safe, cabinet or room which is so constructed and maintained in accordance with the Safe Custody Regulations. However, the Regulations provide an exemption from the stringent storage requirements for controlled drugs when they are “under the direct personal supervision of a pharmacist.” Supplementing the word “supervision” with the words “direct” and “personal” indicates a high degree of control. Therefore, pharmacists must be able to exercise continual supervision of controlled drugs at all times and controlled drugs should only be out of the controlled drug cabinet while they are actually being dispensed.

The requirement for safe custody, for certain controlled drugs, applies equally to patient returned controlled drugs. Until such time that patient returned controlled drugs, (that require safe custody), can be destroyed by being denatured and being rendered irretrievable, they too must be kept in the controlled drug cabinet. Patient returned controlled drugs must be kept segregated from stock controlled drugs, and clearly marked as such, to minimise the risk of errors and inadvertent supply.

The specifications with which safes, cabinets and rooms must comply are given in great detail in the Misuse of Drugs (Safe Custody) Regulations 1973. However, the owner of a pharmacy may elect to apply, as an alternative, to the police for a certificate that his safes, cabinets or rooms provide an adequate degree of security. Applications must be made in writing. The certificate may specify conditions to be observed.

5. The Supply of Controlled Drugs on Prescription

Prescriptions are necessary for controlled drugs, which are prescription only medicines, (except for some Schedule 5 controlled drugs in certain circumstances). The requirements of both the Misuse of Drugs Act 1971 and the Medicines Act 1968 must be satisfied for controlled drug prescriptions.

However, a particular product may have a Marketing Authorisation that permits its supply over the counter (as a P or GSL medicine) without a prescription being required.

For certain preparations (from the list of Schedule 5 controlled drugs) that are highly diluted, a prescription is not required under the Medicines Act 1968 or the Misuse of Drugs Regulations 2001, as amended. For the remaining Schedule 5 controlled drugs and those above the specified dilution limits, a prescription **is** required under the Medicines Act 1968.

Under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001, as amended, only certain persons are lawfully permitted to combine (compound) controlled drugs. Pharmacists are listed as persons who may carry out such compounding. A pharmacist must not provide a patient with the raw ingredients, (controlled drugs), to produce a final extemporaneous medicinal product for their own use. Raw controlled drug ingredients must not be provided, even where the supply of these items is the intention of the lawful prescription.

The Home Office has confirmed that a patient cannot legally compound and extemporaneously prepare a medicinal product that includes a controlled drug even where the ingredients have been lawfully supplied against a prescription, as to do so would be in breach of the legislation.

Pharmacists who choose to compound a controlled drug must ensure that they act in accordance with the Code of Ethics and Section 4 of the “Professional Standards and Guidance for the Sale and Supply of Medicines” document. They must also ensure that such activities are adequately covered by professional indemnity insurance. If the item in question is extemporaneously prepared methadone mixture, pharmacists must also comply with Appendix 1 of this guidance document.

As an alternative to personally compounding controlled drugs, pharmacists may make arrangements for such products to be lawfully prepared by an appropriately licensed “specials” manufacturer.

It is an offence for a practitioner to issue a prescription for a Schedule 2 or 3 controlled drug, (with the exception of temazepam) or for a pharmacist to dispense it, unless it complies with the following requirements:

(i) It shall be written so as to be indelible, be dated and be signed by the person issuing it with his usual signature.

Notes: It remains 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 them self that it is genuine.

*The body of the prescription may be computer generated, including the date. Computer generated dates **are** acceptable. Whilst technically, the body of the prescription may be written by a person other than the doctor, or by using a rubber stamp, **and then** be signed by the prescriber, the Department of Health do not consider this to be desirable. They have recommended that a controlled drug prescription is written by a prescriber who is authorised to write a controlled drug prescription.*

*All prescription requirements (as detailed below), still apply to Schedule 2 and 3 controlled drug prescriptions, (except for prescriptions for temazepam preparations). The prescribing doctor must see and sign the prescription **after** it has been written (or computer generated) and **before** it is issued.*

For additional information on prescriptions that are incomplete or incorrectly written see the Technical Errors section, on pages 16 and 17.

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

(ii) Specify the address of the person issuing it.

Notes: The address of the prescriber must be within the United Kingdom except for Schedule 4 and 5 controlled drugs. (N.B. the United Kingdom does not include the Channel Islands or the Isle of Man).

Whilst it is legally acceptable for the prescription to be stamped or pre-printed with the details of one doctor and signed by a different prescribing doctor, their addresses must be the same. However, the Department of Health does not consider this to be best

practice. In addition, in the case of a private controlled drug prescription, the relevant prescriber's private identification number must appear on the prescription also (see Section 8 - Additional Requirements for Private Controlled Drug Prescriptions).

There is no legal requirement for the prescriber's name to appear on the prescription (other than in the form of their signature). However, it would be good practice for the prescriber's name to appear clearly on the prescription to enable an accurate entry to be made in the controlled drug register (or the prescription only medicine register) of the person authorising the supply, and for any queries that arise regarding the prescription to be addressed.

(iii) Have written thereon, if issued by a dentist, the words "for dental treatment only".

Notes: Any requests for controlled drugs for which no recognised dental use exists should be challenged. In cases of difficulty the Home Office (Telephone Number 020-7035-0464 or 020-7035-4848) or the General Dental Council (Telephone Number 020-7887-3800) 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 their care.

Notes: For further information on veterinary prescriptions see *Veterinary Prescriptions Section, Section 20.*

(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.

Notes: In some cases, a patient will not have "an address". It is generally accepted that in those circumstances "No fixed abode", (or "N.F.A.") would comply with the requirements.

Some hospitals issue outpatient prescriptions with addressographs (pre-printed sticky labels), which contain the patient's name and address. The Home Office has confirmed that technically, legislation would not prevent the use of these for controlled drug prescriptions. The Home Office advises that it must be ensured that the labels are used efficiently and appropriately. In England and Wales, the Department of Health guidance is that good practice would require that if and where sticky labels are used, the labels need to be tamper evident should an attempt be made to remove them. If such a label is used, the prescriber should also sign on the label or at least start his or her signature on the label.

In Scotland, because all prescriptions are scanned by NHS National Services Scotland, the use of adhesive labels in the above way is **not** acceptable.

(vi) Specify the dose to be taken.

Notes: The dose does not legally need to be expressed in both words and figures.

The Home Office opinion is that doses written as: “to be taken as directed”, or: “to be taken when required”, or: “to be taken as per chart” are not acceptable; however, a dosage written as: “one to be taken as directed / when required” or “1 to be taken as directed / when required” or “one to be taken as per chart” or “1 to be taken as per chart” 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. For example, “Four ampoules to be used in a syringe driver as directed” would be acceptable.

However, the Home Office has specified that providing a period of time over which the controlled drug should be used would make the direction clearer. For example, “Four ampoules to be used in a syringe driver over 24 hours as directed” would be clearer.

(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 is not acceptable, but MST Continus tablets is. MST Continus is also available as a suspension / sachet.*

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, the strength must be specified on the prescription. However, 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 to avoid ambiguity, for example:

MST Continus tablets 40mg x 50 (fifty) tablets is unacceptable.

MST Continus tablets 10mg x 50 (fifty) tablets, and MST Continus tablets 30mg x 50 (fifty) tablets, is the best practice and a more acceptable format for such a prescription.

(ix) Either:

(a) 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.

Or:

(b) In any other case, the total quantity (in both words and figures) of the controlled drug to be supplied. (See pages 15 and 16, for section on Technical Errors).

Notes: The Home Office is 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 and for liquids, (such as methadone mixture), the millilitre (ml) is the dosage unit in which the total quantity should be expressed.

For liquids, the use of an abbreviation, such as ml, is acceptable so long as the prescription remains unambiguous and the prescriber's intention is clear.

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, for example:

MST Continus tablets 10mg x 100 mg (one hundred milligrams) is unacceptable.

The total quantity must be expressed as MST Continus tablets 10mg x 10 (ten) tablets, to be acceptable.

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 Home Office has advised that the total quantity can also be expressed as the multiplication of two numbers. However, if the total quantity has been written in this way, the quantity must be written fully in words and be completely clear and unambiguous. For instance:

(2 x 30), (two times thirty); or

2 x packs of 60, (two packs of sixty).

The Home Office has indicated that the use of an asterisk () to indicate a multiplication can be ambiguous, therefore (2*28) should **not** be used to indicate a quantity of (2 x 28).*

Other Prescription Considerations

Name of Prescribed Item

It is good practice that the name of the item prescribed should be written in full, as it appears in the manufacturer's summary of product characteristics (SPC). For instance:

"MST tablets 10mg" would not be acceptable where the prescriber's intention is that "MST Continus tablets 10mg" were to be supplied.

Or: "Morphgesic tablets 10mg" would not be acceptable where the prescriber's intention is that "Morphgesic SR tablets 10mg" were to be supplied.

The name of the item should appear in full, and if it does not, this is not something that a pharmacist can amend or add, (see section below on *Technical Errors*). The full names of products can be found in publications such as the British National Formulary, (BNF), or monthly price lists such as the Chemist & Druggist, (C&D). These publications are not comprehensive and exhaustive. Therefore, if a product does not appear in these publications, pharmacists should consider the possibility that the product may be new to the market, not in the agreed formulary or may be an unlicensed product.

Technical Errors

Where a prescription (for a Schedule 2 or 3 drug, except temazepam), is received which contains a technical error, the pharmacist is only permitted to correct the following:

- (i) a minor typographical error;
- (ii) a spelling mistake;
- (iii) Where the total quantity of the preparation of the controlled drug, or the number of dosage units, as the case may be, is specified in either words or figures, but not both, (i.e. one or the other has been omitted), either the words or the figures can be added to the controlled drug prescription.

Pharmacists can make a supply against a prescription containing these technical errors provided that:

- (a) having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that the prescription is genuine;
- (b) having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that the supply of the drug will be in accordance with the intention of the person issuing the prescription;
- (c) the pharmacist amends the prescription in ink or otherwise indelibly to correct the minor typographical errors or spelling mistakes or so that the prescription complies with the requirement to contain the total quantity of the preparation or the number of dosage units in both words and figures; and
- (d) the pharmacist marks the prescription so that the amendment that they have made under (c) is attributable to them self.

Where a pharmacist makes such a technical amendment, the Regulations do not specify exactly how the prescription should be marked. A pharmacist may choose to write their

registration number or signature on the prescription, or place an asterisk by the change and place details as a footnote on the prescription.

Where one pharmacist makes an amendment, and a second pharmacist makes a supply against such a prescription, the Home Office has stated that both pharmacists should mark the prescription to indicate that the amendment is attributable to them both.

For any other amendment or omission, the prescription should be returned to the person who originally signed the prescription to amend it. The pharmacist cannot add the date where it is omitted from the prescription. If a dose, form or strength is incorrect or omitted the pharmacist cannot amend these errors and the prescription should be returned to the prescriber.

The Home Office has expressed the view that if an amendment cannot be made by the original prescriber, in an emergency, another prescriber who also has the authority to prescribe controlled drugs may make any amendments, or replace anything omitted.

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

Any ambiguities on a controlled drug prescription should be clarified with the prescriber and the appropriate amendments made prior to supply.

Prescribing for up to 30 days' clinical need

Although not a legal requirement, the Department of Health has issued a strong recommendation that as good practice the quantity of Schedule 2, 3 and 4 controlled drugs prescribed should not exceed 30 days' supply. Prescribers will need to be able to justify on the basis of clinical need and believe that it would not pose an unacceptable risk to patient safety to request a supply of more than 30 days. Prescribers have been advised that the reason for prescribing in excess of 30 days' supply should be noted in the patient's notes and should be ready to justify their reason for prescribing in this way.

It is still legal to dispense Schedule 2, 3 and 4 controlled drug prescriptions calling for more than 30 days supply as there may be circumstances where there is a genuine need to prescribe in such a way. Pharmacists should exercise their professional judgement and assess both the prescription and the situation to check the suitability for the patient. As with all prescriptions, if a pharmacist is concerned that the prescription may not be appropriate, the prescriber should be contacted.

Endorsements to be included on a prescription

Each time a Schedule 2 or 3 controlled drug is supplied, the date of supply must be marked on the prescription.

Prescriber and patient identification numbers to be included on prescription

Currently there is no requirement for a prescriber's NHS identification number to appear on NHS controlled drug prescriptions. However, this may change in the future.

A private prescription, for a Schedule 2 or 3 controlled drug for human use, that is to be dispensed in a community setting, must include the private prescriber's identification number – see Section 8 – *Additional Requirements for Private Controlled Drug Prescriptions*.

In England and Wales, there is a requirement for a private prescriber's identification number to appear on a private prescription for a Schedule 2 or 3 controlled drug. This number is a specific number issued by the prescription processing authority which prescribers obtain from the local Primary Care Organisation. In Scotland, a valid NHS prescriber code is used where available, and the new prescriber identification numbers are issued to prescribers where necessary. See Section 8 – *Additional Requirements for Private Controlled Drug Prescriptions*.

There is no current legal requirement for a patient's NHS number to appear on NHS prescriptions (and private prescriptions, if the patient has such a number), although the Department of Health has advised that it should be present as a matter of good practice. Again, this may be made a compulsory requirement in the future.

Any changes to the legal requirements for a controlled drug prescription will be communicated via further guidance, bulletins or announcements.

Validity of prescriptions

It is an offence under legislation for a pharmacist to supply a Schedule 2, 3 or 4 controlled drug before, or later than, 28 days after the appropriate date on the prescription.

The appropriate date, in these circumstances, is defined as:

“the later of the date on which it was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied”.

Where a prescriber wishes the 28 day period to start on a date other than the date of signing, the prescriber may specify a start date from which the period will begin. It is possible that the 28 day period may be specified to begin more than 28 days after the date of signing.

With respect to instalment prescriptions, the first supply must be made within 28 days of the appropriate date. The remainder of the instalments must be dispensed only in accordance with the directions on the prescription.

For Schedule 4 controlled drugs, if the prescription is repeatable, the prescription cannot be dispensed for the first time after the 28 day period. If the first dispensing occurred within the 28 day period, the repeats are legally valid indefinitely, unless the prescriber had stipulated any conditions to the contrary. Depending on the time period that had elapsed, the pharmacist would need to make a professional decision whether it was still appropriate to make a supply, or whether it would be in the patient's best interest to be referred back to the prescriber.

For Schedule 5 controlled drugs (and other non-controlled drug items on a prescription), if the prescription is repeatable, the prescription cannot be dispensed for the first time after more than six months after the appropriate date. If the first dispensing occurred within the 6 month period, as above, the repeats are legally valid indefinitely, unless the prescriber had stipulated any conditions to the contrary. Depending on the time period that had elapsed, the pharmacist would need to make a professional decision whether it was still appropriate to make a supply, or whether it would be in the patient's best interest to be referred back to the prescriber. If the prescription is not repeatable, the prescription cannot be dispensed after the six month period.

Validity of Owings:

The restriction in legislation, as described above, preventing a pharmacist supplying a Schedule 2, 3 or 4 controlled drug later than 28 days after the appropriate date on the prescription, also applies to owing balances on prescriptions. It has been confirmed by the Home Office that the balance / remainder of a Schedule 2, 3 or 4 controlled drug prescription **cannot** be supplied after this time period.

It would be advisable for pharmacists to make the patient or their carer or representative aware that they will not be able to obtain the remainder of a controlled drug prescription after the 28 day time period has elapsed. It would also be advisable that arrangements should be made and procedures put in place to reduce the possibility that a patient will lose part of their prescription. Where there is a balance owing on a Schedule 2, 3 or 4 controlled drug the patient, carer or representative should be advised at the outset that they must return to collect their owing before the 28 day validity lapses.

For Schedule 5 controlled drugs, (as for other non-controlled drug items on a prescription), the balance of an owing cannot be collected more than six months after the appropriate date. If the prescription is repeatable, and the first dispensing occurred within the six month period, the repeats are legally valid indefinitely, unless the prescriber had stipulated any conditions to the contrary. However, again as above, depending on the time period that had elapsed, the pharmacist would need to make a professional decision whether it was still appropriate to make a supply, or whether it would be in the patient's best interest to be referred back to the prescriber.

Collection of Schedule 2 and 3 Controlled Drugs

On collection of a Schedule 2 controlled drug, it is a legal requirement for the pharmacist asked to supply the drug on prescription to ascertain whether the person collecting is the patient, the patient's representative or a healthcare professional acting in his capacity on behalf of the patient, prior to making a supply against the prescription.

Where a patient or their representative (other than a healthcare professional acting in their professional capacity as such) is collecting the controlled drug, the pharmacist may request evidence of that person's identity, and may refuse to make the supply if he is not satisfied as to the identity of that person. This means that pharmacists will have discretion to decide whether to ask for proof of identity and also the discretion to supply the controlled drug even if there is no ID available, or refuse to supply if they are not satisfied as to the identity of the person collecting.

Where a healthcare professional acting in their capacity as such is collecting the controlled drug on behalf of the patient, the pharmacist must obtain the healthcare professional's name and address, and unless acquainted with that professional, must request evidence of that professional's identity. The pharmacist may proceed with the supply even if he is not satisfied as to the healthcare professional's identity.

Types of ID that may be considered suitable include:

- Professional registration number for a healthcare professional
- Driving licence (including photocard section)
- Any official photo ID
- Passport
- Cheque guarantee, debit or credit card
- Birth / marriage certificate
- Cheque book
- Utility bills (two different ones but NOT mobile phone statement)
- Pension or benefit book
- Council tax payment book
- Recent bank or building society statement (within last 6 months)
- Bank or building society book
- Store charge card (not a loyalty card)
- Council rent book
- National savings book

A requirement to record in the controlled drug register whether the person collecting a Schedule 2 controlled drug is the patient, the patient's representative or a health care professional will come into force on the 1st February 2008.

Similarly, requirements to record whether evidence of the patient or their representative's identity was provided and to record the name and address of the health care professional collecting the Schedule 2 controlled drug will come into force on the 1st February 2008.

From 1st February 2008 the following details concerning the collection of Schedule 2 controlled drugs must be recorded in the controlled drug register:

- (a) whether the person collecting the controlled drug was the patient, the patient's representative or a healthcare professional;
- (b) where the person collecting was a healthcare professional, their name and address;
- (c) whether proof of identity was requested from the patient or the patient's representative; and
- (d) whether proof of identity of the person collecting was provided.

Following a review by the Home Office, the required form of the controlled drug register will change from 1st February 2008. See Section 13 – *Controlled Drug Registers* for further information.

Schedule 2 and 3 controlled drug prescriptions have a space on the reverse of the form for the person collecting to sign. There is no legal requirement for a signature on collection, but it is good practice to obtain one. The pharmacist must exercise their discretion as to whether or not to make a supply if the collector does not sign the back of the prescription.

Ideally, it should normally be the patient who signs for the collection on the back of the prescription. However, if that is not possible, then the patient may nominate a person to do this on their behalf and this could be the delivery driver, or another representative.

As with any delivery scheme, there should be a robust audit trail in place, so that when the driver hands the medicine to the patient / patient's representative or carer, this is documented. Wherever possible a signature should be obtained indicating safe delivery of the medicines.

Supplementary Prescribers

A supplementary prescriber is permitted when acting under and in accordance with the terms of a clinical management plan (CMP) to administer and / or supply controlled drugs in Schedules 2, 3, 4 and 5.

Nurse Independent Prescribers

Nurse independent prescribers can prescribe, administer or supply the following controlled drugs, solely for the medical conditions indicated:

- i) Diamorphine hydrochloride (orally or parenterally), morphine (morphine hydrochloride rectally; morphine sulphate orally, parenterally or rectally) or oxycodone hydrochloride (orally, parenterally or rectally) for use in palliative care;
- ii) Buprenorphine (by transdermal route), or fentanyl (by transdermal route), in palliative care;
- iii) Diamorphine hydrochloride (orally or parenterally), or morphine (morphine hydrochloride rectally; morphine sulphate orally, parenterally or rectally), for pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief;
- iv) Chlordiazepoxide hydrochloride (orally), and diazepam (orally, parenterally or rectally), for treatment of initial or acute alcohol withdrawal symptoms;
- v) Codeine phosphate (orally), dihydrocodeine tartrate (orally), and co-phenotrope (orally), (no restriction on medical conditions);
- vi) Diazepam (orally, parenterally or rectally), lorazepam (orally or parenterally), or midazolam (parenterally or via buccal route), for use in palliative care or treatment of tonic-clonic seizures.

Note: A Nurse Independent Prescriber, (NIP), (formerly an extended formulary nurse prescriber in England and Scotland; or in Wales, a supplementary nurse prescriber who has undertaken further training to achieve further qualification as a NIP), should not be confused with the general term independent nurse prescriber (INP). An INP consists of community practitioner nurse prescribers, district nurses and health visitors who have had specialist training to prescribe medicines from a list known as the Nurse Prescribers' Formulary. This qualification is now part of the training to become a district nurse or health visitor and so in the future all district nurses and health visitors will be able to prescribe from this list of medicines.

Pharmacist Independent Prescribers

Currently, pharmacist independent prescribers cannot prescribe, administer in their own right or direct the administration of any controlled drugs. The restriction applies to all controlled drugs including Schedule 5 controlled drugs (that may appear in pharmacy only preparations that are available for over the counter sale).

Following a consultation, this situation is currently being reviewed, and is likely to change. Further guidance will be issued when amendments to legislation have been made.

6. Repeat Prescriptions

Schedule 2 and 3 controlled drugs

Repeat prescriptions are never allowed for Schedule 2 or Schedule 3 controlled drugs, (including temazepam).

Repeats requested on private prescriptions are not permitted.

Schedule 2 and 3 controlled drugs cannot be included in the National Health Service (NHS) Repeat Dispensing scheme that currently operates in England and Wales.

Whilst a prescription for a Schedule 2 or 3 controlled drug cannot request a repeat, there is provision for an instalment prescription to enable a Schedule 2 or 3 controlled drug to be issued over a period of time. It is possible for these to be written on a private standardised prescription form. For further information on private standardised prescription forms, see Section 8 – *Additional Requirements for Private Controlled Drug Prescriptions*. For further information on NHS instalment forms, see Section 7 – *Dispensing for Drug Misusers*.

Schedule 4 and 5 controlled drugs

Repeat prescriptions are allowed for Schedule 4 or Schedule 5 controlled drugs, whether prescribed privately or on the NHS in England and Wales, (Repeat Dispensing Scheme).

For Schedule 4 controlled drugs to be supplied legally against a valid repeatable prescription, the first dispensing must occur within 28 days of the appropriate date on the prescription. The remaining dispensings will not have an expiry date unless the prescriber has specifically included a date on the prescription after which supplies should not be made.

For Schedule 5 controlled drugs, the first dispensing must be within 6 months of the appropriate date on the prescription as for non-controlled drug prescriptions. The remaining repeats are legally valid indefinitely, unless the prescriber has stipulated otherwise.

In situations where pharmacists are asked to dispense legally valid repeats after extended time periods, the pharmacist must consider the appropriateness of making a supply. As with all prescriptions, if the pharmacist is concerned about the suitability of a prescription, the prescriber should be contacted.

7. Dispensing for Drug Misusers

A person is regarded as being addicted to a drug if, and only if, the person has as a result of repeated administration become so dependent on a drug that the person has an overpowering desire for the administration of it to be continued.

There is provision for misusers to receive daily supplies of certain controlled drugs on special prescriptions. This is an administrative arrangement under the National Health Service and does not form part of the Misuse of Drugs Regulations 2001, as amended.

The types of prescription forms used for instalment prescribing and drugs that can be prescribed by instalment differ between England, Scotland and Wales.

Note: Diamorphine, dipipanone and cocaine can only be prescribed for the treatment of addiction by specially licensed doctors. Confirmation of this status can be obtained from the Drug Licensing Unit of the Home Office, (via the Home Office switchboard. Telephone number can be found in Appendix One, on page 51). Where these drugs are being used for the treatment of organic disease or injury, no such licensing is required and any doctor can prescribe them.

Scotland

Currently the types of prescription forms in use in Scotland to prescribe by instalment on the NHS are:

(a) GP10 are issued by General Practitioners, (GPs). Any medicine normally prescribable on a GP10 can be prescribed by instalment on a GP10, including Schedule 2, 3, 4 and 5 controlled drugs.

(b) GP10-SS are issued by General Practitioners, (GPs). They are intended for use as computer generated prescriptions, although they can still be handwritten.

(c) GP10(COMP) are issued by General Practitioners, (GPs). They are intended for use with laser printers, but are soon to be withdrawn.

(d) GP10(N) are issued by Nurse Independent Prescribers and Nurse Supplementary Prescribers.

(e) GP10(N)-SS are issued by Nurse Independent Prescribers and Nurse Supplementary Prescribers. They are intended for use as computer generated prescriptions, although they can still be handwritten.

(f) GP10(P) are issued by Pharmacist Supplementary Prescribers.

(g) HBP(A) are issued from drug addiction clinics and can be used to prescribe, in instalments, any drug used in the treatment of addiction.

(h) HBP(A)-SS are issued from drug addiction clinics. They are intended for use as computer generated prescriptions, although they can still be handwritten.

(i) HBP are issued from hospitals by hospital based prescribers and can be used to prescribe, in instalments, any drug used in the treatment of addiction.

(j) HBP-SS are issued from hospitals by hospital based prescribers. They are intended for use as computer generated prescriptions, although they can still be handwritten.

(k) HBP(N) are issued from hospitals by hospital based Nurse Independent Prescribers and Nurse Supplementary Prescribers.

(l) HBP(N)-SS are issued from hospitals by hospital based Nurse Independent Prescribers and Nurse Supplementary Prescribers. They are intended for use as computer generated prescriptions, although they can still be handwritten.

(m) HBP(P) are issued from hospitals by hospital based Pharmacist Supplementary Prescribers.

There are no limits to the number of days' treatment that can be supplied against these prescriptions. However, the Scottish Executive has stated that as a matter of good practice the amount of controlled drug prescribed on a prescription should not exceed 30 days supply. (This limit can be exceeded if the prescriber believes that such a supply is clinically indicated and would not pose an unacceptable risk to patient safety, see Section 5 – *The Supply of Controlled Drugs on Prescription, Prescribing for up to 30 days' clinical need*, page 17).

England

Currently the types of prescription forms in use in England to prescribe any Schedule 2 controlled drug, buprenorphine and diazepam by instalment on the NHS are:

(a) FP10(MDA)-S are issued by General Practitioners. No other items are prescribable on this form other than water for injection supplied with dry powder injections which should be supplied in a single instalment. Where a dry powder injection is ordered, pharmacists may supply sufficient water for injection even when not specifically requested by the prescriber. The prescription should be endorsed with the quantity of water supplied in order to ensure payment.

(b) FP10(MDA)-SS are issued by supplementary prescribers, hospital prescribers and GPs. They are intended for use as computer generated prescriptions, although they can still be handwritten. Other drugs and allowed drug tariff items can be ordered on this form but not in instalments. Only one dispensing fee will be paid for supplying any other item.

(c) FP10(MDA)-SP are issued by supplementary prescribers. They are intended for use as handwritten controlled drug instalment prescriptions.

(d) FP10H(MDA)-S are issued by hospital prescribers.

A maximum of 14 consecutive days' treatment may be ordered. If more than 14 days' supply is prescribed it is understood that the pharmacist will be reimbursed for the quantity of controlled drug supplied but that the Prescription Pricing Division of the NHS Business Services Agency (PPD-NHSBSA) will refer the prescriber to the Primary Care Trust. It is therefore advisable that the prescription be amended by the prescriber.

Please see pages 16 and 17 for guidance on errors and omissions on prescriptions.

Wales

Currently the types of prescription forms in use in Wales to prescribe by instalment on the NHS are:

(a) WP10(MDA) are issued by General Practitioners. These forms can be used to prescribe any Schedule 2, 3, 4 or 5 controlled drugs by instalments.

(b) WP10HP(AD) are issued by hospital / clinic based prescribers. These are intended to be used to prescribe Schedule 2 controlled drugs, but pharmacists will be reimbursed if drugs in Schedule 3, 4 or 5 are prescribed in instalments.

A maximum of 14 days' consecutive treatment may be ordered on one form.

General Guidance and Requirements

Practitioners will often wish a patient being treated for addiction to always attend the same pharmacy, in order to monitor patient compliance. Sometimes a prescription will have the name of a particular pharmacy written at the top by the prescriber, by prior arrangement with the pharmacy quoted and with the patient's consent. This is not a legal direction and the prescription could be dispensed lawfully at a pharmacy other than that which is named, provided that the supplying pharmacist checks that this is acceptable to both patient and prescriber.

All the prescription requirements previously discussed must be complied with. The controlled drug is often ordered to be dispensed in daily instalments and the prescription must contain a direction specifying *the amount* of the instalment which may be supplied and *the intervals* to be observed when supplying.

It is not a legal requirement for *the number* of instalments to be specified.

The Home Office has expressed the view that the instalment amount should be written as a total number. The amount of the instalment **should not** be written as a multiplication of the daily dose. For example where a prescription specifies a daily dose of 50ml of methadone mixture to be picked up once a week, the amount of the instalment **should not** be written as "supply 7 x daily dose on Monday ..." but should be written as "supply 350ml on Monday...".

The first instalment must be dispensed within 28 days of the appropriate date on the prescription. The prescription must be marked with the date of each dispensing, an entry made in the controlled drug register, and records retained for two years after the supply of the last instalment.

Although there is no legal requirement for a starting date to be specified, where one is given on the prescription it must be complied with and the instalments run from that date. In every other case the instalment direction will run from the date of first dispensing.

The instalment prescription must be dispensed on the due date specified on the prescription. If a drug misuser fails to collect on the specified day, then that day's supply is forfeited and the prescription should be marked as "not dispensed". Where a prescription orders several days supply to be collected on a particular day and the drug misuser does not collect on the due date then the whole instalment is forfeited and the drug misuser cannot have the remainder of the instalment, (however, see below for an exception to this).

A typical instalment prescription may read as follows:

Methadone Oral solution 1mg/1ml	<i>name, form, strength.</i>
20ml to be taken daily	<i>dose and frequency.</i>
Supply 20ml daily from 6 th August	<i>instalment directions (amount and interval to be observed).</i>
40ml to be supplied on Saturday 11 th August and Saturday 18 th August	<i>allowance for closures (see alternative possible wording to allow for closures below).</i>
280ml (two hundred and eighty millilitres)	<i>total quantity in words and figures.</i>

Home Office approved wording for instalment prescriptions

There is a legal requirement that each supply against an instalment prescription must be dispensed on the due date specified on the prescription. However, the Home Office has confirmed that approved wording can be used by those prescribing controlled drugs by way of instalments that is compliant with the Misuse of Drugs Regulations 2001, as amended, which will enable those supplying controlled drugs to issue the remainder of an instalment prescription when the person has failed to collect the instalment on the specified day.

This text is in addition to the usual controlled drug prescription requirements. Although the approved form of words shown below is not a mandatory requirement under the Misuse of Drugs Regulations 2001, as amended, **if a prescription does not contain this wording, or other similar wording approved by the Home Office, the Regulations only permit the supply to be in accordance with the prescriber's instalment direction.**

Approved wording reads as follows:

For supervised consumption:

“Supervised consumption of daily dose on specified days; the remainder of supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the day(s) missed may be supplied.”

For unsupervised consumption:

“Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e., the instalment less the amount prescribed for the day(s) missed) may be supplied.”

For when the pharmacy is closed:

This approved wording will enable those supplying controlled drugs to issue instalments on the day immediately prior to closure should the pharmacy be closed on days when instalments are due. The wording approved by the Home Office is:

“Instalments due on days when the pharmacy is closed should be dispensed on the day immediately prior to closure.”

This wording can be used where a supply is requested for a day on which the pharmacy is closed. For example, if the prescription stated: *“140ml to be dispensed on Mondays”*, and the Monday in question was a bank holiday on which the pharmacy was shut, (and the pharmacy was also shut on Sundays), the instalment could be supplied on the day before closure.

Therefore, the weekly instalment could be supplied on the Saturday, immediately before the bank holiday. In the case of a prescription for a daily pickup and the pharmacy was closed on the Sunday and Monday, the prescription would have to contain a direction that instalments due on the days when the pharmacy is closed should be dispensed on the day immediately before closure.

Where a prescription contains wording that is different to the sentence reproduced above, the Home Office must be contacted to seek approval for the wording in question. Approval must be confirmed before supply is made against such instruction.

Pharmacists are also reminded that they have a professional responsibility to ensure that patients are provided with sufficient information and advice to enable the safe and effective use of their medicine. Therefore, where a bottle of medicine contains more than one dose, the pharmacist should ensure that the patient is able to correctly measure out their required doses themselves.

Advice regarding missed doses

When providing services to drug misusers it is important to remember that several missed doses of methadone may cause a reduction in tolerance.

In the event that a patient fails to collect several days' supplies of methadone consecutively, pharmacists must consider the patient's best interests and whether tolerance levels may be affected and whether there is a need to inform the prescriber.

In the event that a patient has not provided prior consent for their prescriber to be informed of situations where they miss one or more doses, pharmacists should explain to the patient why there is a need to inform their prescriber and attempt to seek their consent to do so. Where a patient refuses to provide consent for disclosure, pharmacists must weigh up their duty of confidentiality to the patient with the need to act in their best interests, and be prepared to justify their decision.

Pharmacists should consider the benefits of a written agreement between themselves, the patient, and the prescriber or drug worker for the service to be provided, which should include the protocol to be followed when a patient does not collect their daily dose or misses a number of doses of methadone.

The Royal College of General Practitioners has issued guidance regarding supplies of methadone and the need for reassessment and re-titration if a patient consecutively misses doses. This guidance can be found at: www.rcgp.org.uk/PDF/drug_meth%20guidance.pdf .

Collection by representatives

Occasionally a drug misuser will send an agent to collect an instalment of a controlled drug on his or her behalf. The Misuse of Drugs Regulations permit the possession of a controlled drug by a person who is conveying it to someone else authorised to possess. This provision allows an agent to act on behalf of the patient.

However, when supply is for treatment of a drug misuser, it is advisable to obtain a letter of authorisation from the drug misuser before making a supply to his agent. Such documents can assist both the medical profession and the enforcement authorities in the proper management of supplies to drug misusers.

Pharmacists must of course, be satisfied that the letters of authorisation are genuine and should be wary of patients who are using many different agents. A separate letter of authorisation should be obtained on each occasion a supply is made to the agent, and retained for a period so that a comparison of signatures can be made.

It may be wise to insist that the patient attends personally at least once a week, unless the pharmacist knows that this is not possible.

Supplying Drug Paraphernalia

Legislation permits pharmacists when acting in their capacity as such to supply specified drug paraphernalia to illicit drug users. The items that can be supplied are:

- swabs;
- utensils for the preparation of controlled drugs;
- citric acid;
- ascorbic acid; and
- filters.

And legislation permits pharmacists, if they are employed or engaged in the lawful provision of a drug treatment service, only in the course of those services, to supply:

- ampoules of sterile water for injection, (on the condition that each ampoule does not contain more than 2ml).

A pharmacist who is not engaged or employed in such services, can only supply ampoules of sterile water for injection on a prescription.

8. Additional Requirements for Private Controlled Drug Prescriptions

Private Prescriptions for the Treatment of Addiction

All the previously discussed legal requirements apply with equal force to private prescriptions. However, there are additional requirements which apply to private prescriptions for Schedule 2 and 3 controlled drugs, detailed in this Section. A private prescription can be used to order controlled drugs in instalments and the appropriate dispensing fee can be charged by the pharmacist for each instalment dispensed.

Private Prescription Requirements

In the case of a private prescription for a Schedule 2 or 3 controlled drug, intended to be dispensed in a community setting, the following requirements also apply:

(i) The Schedule 2 or 3 controlled drug must be written on the specified private standardised form.

In England the form is called an FP10PCD. In Scotland the form is called a PPCD(1). In Wales the form is called WP10PCD and WP10PCDSS.

Since 1st September 2007 there has been a requirement for pharmacists in England, Scotland and Wales to submit the original of Schedule 2 and 3 private prescription forms for human use to the relevant NHS agency (as has been the arrangement in Scotland for some time).

If a pharmacy does not have an NHS contract, they would need to contact the relevant NHS prescription processing authority to obtain a unique code to enable them to send copies of private prescriptions to the appropriate body.

The Primary Care Organisation (PCO) in the area where the prescriber lives or works, is responsible for arranging for the forms to be supplied to private prescribers.

Police doctors

Police surgeons and forensic medical examiners writing private prescriptions containing Schedule 2 and 3 controlled drugs must use the standardised private prescription form.

Hospital prescribers

Private prescriptions for Schedule 2 and 3 controlled drugs written by hospital prescribers, intended to be dispensed at a community pharmacy or within a community setting, must be written on the standardised private prescription form.

(ii) A private prescription for a Schedule 2 and 3 controlled drug (to be dispensed in community) must contain the private prescriber's identification number.

This requirement applies to private prescriptions for Schedule 2 and 3 controlled drugs written in England, Scotland and Wales. In Scotland, a valid NHS prescriber code is used where available, and the new prescriber identification numbers are issued to prescribers where necessary.

For further information, please see the guidance entitled: "Changes in the management of CDs affecting pharmacists England, Scotland and Wales" available on the Society's website at www.rpsqb.org.

Pharmacists are not able to dispense a private prescription for a Schedule 2 or 3 controlled drug for human use issued by a prescriber in England or Wales, unless it contains the private prescriber's identification number. In Scotland, the prescription must contain the appropriate code number before it can be dispensed.

The private prescriber's identification number is **not** the same as the prescriber's professional registration number (such as a GMC registration number) or their NHS prescribing code, (except for the arrangement in Scotland). The identification number is a specific number issued by the prescription processing authority which prescribers obtain from the local Primary Care Organisation.

***Notes:** These requirements (i) and (ii) **do not apply** to prescriptions written by veterinary practitioners or veterinary surgeons.*

*These requirements (i) and (ii) **do apply** to private prescriptions for temazepam, (in addition to all Schedule 2 and the other Schedule 3 controlled drugs).*

*These requirements (i) and (ii) **do apply** to private dental prescriptions.*

Private Prescription Requirements for Temazepam

See Section 9 - *Temazepam Prescriptions* overleaf.

Prison Arrangements

Prison arrangements in England and Wales:

Where a Service Level Agreement exists between a community pharmacy and a Primary Care Organisation to supply items to a prison, the local Primary Care Organisation should be consulted to determine whether or not it would be necessary to use the standardised private prescription form for such supplies. Whether or not standardised private prescription forms are required, a robust audit trail must be maintained.

Where it is determined that this is a private, (not an NHS), arrangement, prescribers would need to use a standardised private prescription form for Schedule 2 or 3 controlled drugs to be supplied in a community setting. Where the private standardised form is required, the prescriber's identification number would also need to appear on the form.

Prison arrangements in Scotland:

The Scottish Prison Service receives pharmaceutical services privately under a commercial contract with a national community pharmacy chain not through the NHS. The arrangements in this Section that relate to private controlled drug prescriptions do apply to prisons in Scotland. Schedule 2 and 3 controlled drugs must be written on the standardised private prescription form and must include the private prescriber's identification number, (or their NHS prescribing code as has been arranged specifically for Scotland).

9. Temazepam Prescriptions

Private prescriptions for temazepam, intended to be dispensed in a community setting, must be written on the appropriate private standardised form and must contain the private prescriber's identification number.

Apart from these restrictions in relation to the private prescribing of temazepam, both NHS and private prescriptions for temazepam preparations are exempted from the remaining prescription requirements of the Misuse of Drugs Regulations 2001, as amended. This means that the prescription may be endorsed "PC" (Prescriber Contacted) as to the strength, quantity, or dose where any or all of these are omitted from the prescription. The requirements of the Medicines Act 1968 still apply.

Notwithstanding these relaxations, any prescription for temazepam is only valid for 28 days from the appropriate date on the prescription. Under no circumstances, be it on a NHS (repeat dispensing scheme) or private prescription, are repeats allowed for temazepam prescriptions.

10. Fentanyl Patch Prescriptions

The strength on a controlled drug prescription should always be unambiguously expressed so as to clearly identify 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 not the total amount contained in each patch.

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

There are two different formulations available of fentanyl patch:

- i) The original patch called Durogesic, which is also available generically, is a reservoir patch. It is available in several strengths, including the following:
 - Durogesic patch 25 containing a total of 2.5mg of fentanyl (releasing at 25 mcg/hr);
 - Durogesic patch 50 containing a total of 5.0mg of fentanyl (releasing at 50mcg/hr);
 - Durogesic patch 75 containing a total of 7.5mg of fentanyl (releasing at 75mcg/hr);
 - Durogesic patch 100 containing a total of 10.0mg of fentanyl (releasing at 100mcg/hr).

- ii) The more recently introduced Durogesic DTrans patch is a matrix patch. It is available in several strengths, including the following:
 - Durogesic DTrans patch 25 containing a total of 4.2mg of fentanyl, with an active surface area of 10.5cm², releasing at 25mcg/ hr;
 - Durogesic DTrans patch 50 containing a total of 8.4mg of fentanyl, with an active surface area of 21.0cm², releasing at 50mcg/hr;
 - Durogesic DTrans patch 75 containing a total of 12.6mg of fentanyl, with an active surface area of 31.5cm², releasing at 75mcg/hr;
 - Durogesic DTrans patch 100, containing a total of 16.8mg of fentanyl, with an active surface area of 42.0cm², releasing at 100mcg/hr.

If the preparation on the prescription was written as “Durogesic 25 patch”, or “Durogesic 25mcg/hr patch”, the Society would advise that the pharmacist should check with the prescriber as to which product was required. If this was to be the DTrans patch, the prescription would need to be returned before dispensing for the prescriber to add DTrans. Alternatively, this would suffice for the dispensing of the reservoir patch of Durogesic.

If a prescriber writes a prescription requesting “fentanyl 25 patches”, or “fentanyl 25mcg/hr patches”, the Home Office has indicated that a prescription written in this way would comply with the Misuse of Drugs Regulations 2001, as amended. The pharmacist would need to confirm with the prescriber and patient which product was required and then endorse the prescription appropriately. The pharmacist would additionally need to counsel the patient or carer on any possible changes since their last prescription.

The dosage should be expressed in terms of the number of patches to be used and interval between patch applications, for example, “one patch to be applied every 72 hours”. A dose of “every 72 hours” would not be acceptable.

11. Sativex Prescriptions

Currently Sativex, (a Cannabis based oro-mucosal spray), is a Schedule 1 controlled drug under the Misuse of Drugs Regulations 2001, as amended, available as an unlicensed medicine on a named patient basis. On application by the manufacturer, the Home Office has issued an open general licence for this product allowing doctors to prescribe, pharmacists to dispense and patients who are prescribed this to possess it without the need for individual licences to be obtained.

The Home Office anticipates that after the Medicines and Healthcare products Regulatory Agency, (MHRA), have approved and granted Sativex a licence, it will be re-scheduled to become a Schedule 4 controlled drug.

Until any change is approved, the prescription should be written as for a Schedule 2 controlled drug. The Home Office has confirmed that private prescriptions for Sativex to be dispensed in a community setting do not need to be written on the standardised prescription form.

The Home Office has removed the record keeping requirements for Sativex. Therefore no records need to be kept in the controlled drug register.

The Home Office requires that, where a lockable refrigerator is available, Sativex should be stored in it prior to dispensing. Otherwise it should be kept in a fridge not visible to the general public and in an adequately secure (refrigerated) location.

12. Emergency Supplies

Emergency supply of a Schedule 2 or 3 controlled drug to a patient:

Under no circumstances may an emergency supply of a Schedule 2 or 3 controlled drug be made to a patient, other than in the case of the supply of phenobarbitone for the treatment of epilepsy, and only if it does not contain any other substances in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations 2001, as amended.

Emergency supply of a Schedule 4 or 5 controlled drug to a patient:

An emergency supply of a Schedule 4 or 5 controlled drug can be made to a patient, if appropriate, in accordance with the requirements in legislation allowing emergency supplies, detailed in the Prescription Only Medicines (Human Use) Order 1997, as amended. Details of these requirements can be found in Section 1.2 of the Medicines, Ethics and Practice – A guide for pharmacists and pharmacy technicians.

13. Controlled Drug Registers

Records must be kept by pharmacists 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.

These particulars are the minimum fields of information that must be recorded in the controlled drug register. The Regulations do not prevent additional related information being recorded.

From 1st February 2008, the headings under which information must be recorded in the controlled drug register will be as follows:

For controlled drugs obtained the following must be recorded:

- (a) date supply received;
- (b) name and address from whom received;
- (c) quantity received.

For controlled drugs supplied the following must be recorded:

- (a) date supplied;
- (b) name / address of person or firm supplied;
- (c) details of authority to possess – prescriber or licence holder's details;
- (d) quantity supplied;
- (e) person collecting Schedule 2 controlled drug (patient / patient's representative / healthcare professional), and if a healthcare professional collecting a Schedule 2 Controlled Drug, their name and address;
- (f) was proof of identity requested of patient / patient's representative (Yes / No);
- (g) was proof of identity of person collecting provided (Yes / No).

The following points must be complied with in relation to the keeping of controlled drug registers:

- (a) Entries must be in chronological sequence.
- (b) A separate register must be used for each class of drugs. Separate sections are required for amphetamines (which includes dexamphetamine) and methylamphetamine.
- (c) If desired, separate registers can be used for different drugs or strengths of drugs comprised within a class of drugs. (see *Note* below for change that will come into force on 1st February 2008).
- (d) The class of drugs must be specified at the head of each page. (see *Note* below for change that will come into force on 1st February 2008).
- (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, or shall be in a computerised form.
- (h) The computerised form must ensure every such entry is attributable and capable of being audited in accordance with best practice guidance.
- (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. Where the register is in computerised form, it must be accessible from those premises.
- (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 inspection 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.

- (m) Records must be kept in their original form or copied and kept in a computerised form which is in accordance with best practice guidance.
- (n) A copy of the register, in its computerised or other specified form may be requested to be sent to persons authorised by the Secretary of State (e.g. the Society's inspectors).

Note: From the 1st February 2008, the following points must be complied with in relation to the keeping of controlled drug registers:

- (a) In the separate register or, separate part of the register used for each class of drug, a separate page shall be used for each strength and form of that drug. This will replace point (c) in the list above.
- (b) The class of the drug, its strength and form must be specified at the head of each page. This will replace point (d) in the list above.

From the 1st February 2008, entries made in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register.

The following points are good practice in relation to the keeping of controlled drug registers:

- (a) It is good practice that all controlled drug registers contain a running balance.
- (b) Where an entry has been made in the controlled drug register no entry needs to be made in the prescription only register under the Medicines Act 1968, but it is good practice to make such entries.

As an alternative to a bound book, pharmacists may elect to keep their controlled drug register electronically. Electronic controlled drug registers must comply with best practice guidance. Current best practice guidance states that:

- (a) Registers may only be kept in computerised form if safeguards are incorporated into the software to ensure all of the following:
 - the author of each entry is identifiable;
 - entries cannot be altered at a later date; and
 - a log of all data entered is kept and can be recalled for audit purposes.
- (b) Access control systems should be in place to minimise the risk of unauthorised or unnecessary access to the data in computerised registers.
- (c) Adequate backups must be made of computerised registers.
- (d) Arrangements should be made so that inspectors can examine computerised registers during a visit with minimum disruption to the dispensing process.

The most up to date guidance can be found on the National Prescribing Centre website at www.npc.co.uk, the Society's website at www.rpsgb.org and the Department of Health's website at www.dh.gov.uk.

The Home Office is working towards a review of the form of the controlled drug register and further guidance on record keeping will be issued in due course.

Running balances

Running balances are expected to become a mandatory requirement for all controlled drug registers when electronic registers are in common use. Currently, the advice is that pharmacists should maintain running balances as a matter of good practice.

If desired, separate parts of the register can be used for different drugs or strengths of drug comprised within a class of drug (this is recommended to help ensure running balances are effectively maintained and monitored).

Out of date controlled drug stock, must continue to be included in the running balance. Until such time as this stock is destroyed in the presence of an Home Office authorised witness, it remains stock and should be counted in the running balance total.

Discrepancies

The running balance of drug remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals. This should normally be done each week, or more often depending on the volume of controlled drugs dispensed. If discrepancies arise, more frequent reconciliation should be undertaken until the problem is resolved. The pharmacist is responsible for ensuring that appropriate action is taken if discrepancies arise.

Standard Operating Procedures (SOPs) should clearly define the action that should be taken if a discrepancy between the theoretical and actual balance of stock arises, stating, for example, what action the pharmacist should take, when and how the pharmacy owner or superintendent pharmacist should be notified and what records should be made.

Pharmacists who become aware of discrepancies must make checks to ensure that the reasons for the discrepancy are established. If resolved, a note should be made in the register, (by a dated marginal note or footnote), correcting the discrepancy in the balance.

If the discrepancy cannot be resolved or the discrepancy is such that there is immediate cause for concern, the Society inspector, responsible Accountable Officer, police chemist inspection officer, police officer or other appropriate investigating authority should be notified in order that further advice can be given.

Discrepancies are most likely to arise with liquid preparations. Most original packs of liquid preparations have some degree of overage. The Home Office has confirmed that this overage can become part of pharmacy stock, provided appropriate records are made to account for this. The overage should be entered in the obtained section of the controlled drug register.

Spills

Discrepancies in stock levels may arise due to the measurement process or spillages. Where a pharmacist can be satisfied that any loss of liquid is a result of measurement or spillage, a record should be made in the controlled drug register, and the running balance corrected to account for the loss. Whenever possible, spillages should be witnessed and the record initialled by a second person. It would then be advisable to contact the Society's Inspector in the first instance (or the Home Office) for guidance on reconciling the controlled drug register.

Standard operating procedures must be put in place detailing who should be alerted if complications with controlled drugs arise. There must also be systems in place to report untoward incidents involving the management and use of controlled drugs and to alert the accountable officer of any concerns or complaints involving the management and use of controlled drugs.

14. Monitoring and Accountable Officers

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 have brought in new arrangements for the monitoring of the management, usage and other aspects of controlled drugs in England and Scotland. Details of the implementation of Shipman recommendations in relation to monitoring and inspection of controlled drugs in community pharmacies in Wales have yet to be finalised.

In England, these Regulations came into force on the 1st January 2007.

In Scotland, these Regulations came into force on the 1st March 2007.

Monitoring

Under the Regulations, Accountable Officers are responsible for periodic inspections of premises which are used in connection with the management or use of controlled drugs except for those premises that are subject to inspection by the Healthcare Commission, the Commission for Social Care Inspection or the Royal Pharmaceutical Society of Great Britain.

In agreement with the Department of Health, the Society's inspectors have agreed to carry out the monitoring of the management and use of controlled drugs as part of their routine visits to community pharmacies in England and Scotland. They will monitor various aspects of controlled drug management and use, including the following:

- Training of personnel;
- Accountability and Standard Operating Procedures, (SOPs). (see Section 15 for more information on SOPs);
- Security and safe custody;
- Controlled drug stock and assembled medicines procedures;
- Records and audit;
- Procedures for supplies of controlled drugs;
- Destruction;
- Prescribing and over the counter sales of medicines.

During routine monitoring and inspection by the Society's inspectors, a report will be compiled. Any concerns about the management and use of controlled drugs at a pharmacy, will be passed to the relevant Accountable Officer.

The Society will also require a periodic declaration from pharmacy owners in relation to the management and use of controlled drugs within each of their pharmacy premises. Currently, this declaration is part of the annual premises retention fee cycle. In addition, the Society can require an appropriate self assessment to be completed from a registered pharmacy.

More information on the monitoring and inspection of controlled drugs in a community pharmacy setting can be found at the Society's website, at: www.rpsgb.org .

The police retain responsibility for the investigation of crime and misuse of drugs offences that may arise.

Accountable Officers

A number of health care bodies are classified as designated bodies and are required to appoint an Accountable Officer. The bodies that are required to appoint such a person include Primary Care Organisations, (PCOs), such as Primary Care Trusts and Health Boards, as well as independent hospitals, NHS trusts and NHS foundation trusts.

The Accountable Officer is responsible for a range of issues involving safe management and use of controlled drugs within organisations subject to their oversight. The Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) Regulations 2006 legislation place a statutory responsibility on various bodies including the Society to co-operate with Accountable Officers and other responsible bodies, and to share information relating to concerns about controlled drugs.

The other local agencies required to co-operate include healthcare organisations, the police, social service authorities and inspectorates from the Healthcare Commission and the Commission for Social Care Inspection (CSCI).

Accountable Officers in PCOs act as the hub of a local network involving the key local agencies to put this duty into practice. The Accountable Officer must not "routinely supply, administer or dispose of controlled drugs as part of his or her duties". The Accountable Officer can be a person who may have an occasional exceptional need to use controlled drugs in an emergency, but if this is the case, that use should be open to the scrutiny of another person to whom they are answerable.

An Accountable Officer must not be an authorised witness for the purposes of witnessing the destruction of controlled drugs. An Accountable Officer, (in addition to a Secretary of State), is able to authorise a person, or class of persons, to be an authorised witness, (see Section 16 - *Destruction of Controlled Drugs*).

The PCO has a responsibility for the pharmacies within its area with which it has NHS pharmaceutical service contracts. As well as being in charge of certain functions within their own designated body, the Accountable Officer in the PCO is responsible for the management and use of controlled drugs in these pharmacies. These responsibilities include maintaining records of and investigating reported concerns regarding controlled drugs and taking appropriate action where there are well founded concerns. Legislation requires certain records to be kept with regard to occurrence reports detailing the concerns that have been raised. They have a duty to set up local intelligence networks for their area. In Scotland, the Accountable Officers' will also cover organisations contracted with the Health Boards. The Accountable Officer in the PCO also has the duty to ensure that there are adequate destruction and disposal arrangements for controlled drugs.

The Department of Health and the Scottish Executive have recommended that the Primary Care Organisation's Accountable Officer carries out a formal review of primary care providers, (contractors, including for example community pharmacies), contracted with the PCO. The review can be conducted as part of existing clinical governance reviews. This review will be based on the controlled drug declaration and the self-assessment supplied to the Society, as discussed above.

A list of Accountable Officers in England can be found at the following website address:
www.healthcarecommission.org.uk/serviceproviderinformation/controlleddrugs/accountableofficers.cfm .

A list of Accountable Officers in Scotland can be found at the following website address:
www.sehd.scot.nhs.uk/mels/CEL2007_03.pdf .

15. Standard Operating Procedures

Since the 1st January 2007 in England, and since the 1st March 2007 in Scotland, the Controlled Drugs (Supervision of Management and Use) Regulations 2006, require any body or person providing services under arrangements made with a designated body, (such as a pharmacy providing NHS services for a PCO) to have up to date Standard Operating Procedures (SOPs) in place to cover the following matters:

- (a) who has access to the controlled drugs;
- (b) where the controlled drugs are stored;
- (c) security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- (d) disposal and destruction of controlled drugs;
- (e) who is to be alerted if complications arise; and
- (f) record keeping, including –
 - (i) maintaining relevant controlled drugs registers under misuse of drugs legislation, and
 - (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2001, as amended, that have been returned by patients.

The Department of Health, (in England), has issued guidance giving more detailed advice on the areas that may need to be covered by the SOP. The guidance is entitled the “Safer management of controlled drugs: guidance on Standard Operating Procedures for controlled drugs” and is available on the Department of Health’s website at www.dh.gov.uk . It is anticipated that the Scottish Executive Health Department will issue guidance on what should be covered by SOPs in Scotland in due course.

Procedures should be in place detailing how untoward incidents involving controlled drugs are dealt with, and systems should be in place to alert the Accountable Officer of any complaints or concerns involving the management and use of controlled drugs.

Please see the Inspector’s Checklist – Routine Monitoring and Inspection at:
www.rpsgb.org/pdfs/inspvisitschecklist.pdf for further details of procedures that should be in place.

Although the recording of patient returned controlled drugs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2001, as amended, the Controlled Drugs (Supervision of Management and Use) Regulations 2006, as described in (f)(ii) above, require Standard Operating Procedures to be in place for maintaining a record of certain controlled drugs, (Schedule 2), that have been returned by patients.

Pharmacists are therefore advised to keep a record of patient returned Schedule 2 controlled drugs, and their destruction, and to ensure that another member of staff, preferably a

pharmacist or pharmacy technician if available, witnesses the destruction. The record of destruction should be made somewhere other than the controlled drug register – for example at the back of the private prescription register or in a separate book designated for that purpose.

It is recommended that the following details are recorded:

- the date of return of the controlled drugs;
- details of the controlled drugs:
 - (i) name of the controlled drug;
 - (ii) quantity of the controlled drug;
 - (iii) strength of the controlled drug; and
 - (iv) form of the controlled drug;
- the role of the person who returned the controlled drugs (if known);
- the name and signature of the person who received the controlled drugs;
- the patient's name and address (if known);
- the names, positions and signatures of:
 - (i) the person destroying the controlled drugs; and
 - (ii) the person witnessing the destruction; and
- the date of destruction.

The Society recommends that these records be retained for a period of at least 7 years.

Forms to record these details are available from the Society's website at <http://www.rpsgb.org.uk/pdfs/restooldestrcd.pdf> and the NPA can supply a record book for this purpose.

16. Destruction of Controlled Drugs

Obsolete, expired and unwanted stock controlled drugs

Any person required by the Regulations to keep records of controlled 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 and Controlled Drugs Liaison Officers, (certain police officers). Society Inspectors will not routinely witness the destruction of controlled drugs during their monitoring and inspection visits. Pharmacists in England and Scotland should contact the Accountable Officer in their Primary Care Organisation in the first instance to make arrangements for an authorised witness to attend the destruction of controlled drugs.

An Accountable Officer, (in England and Scotland, in addition to a Secretary of State), is able to authorise a person, or class of persons, to be an authorised witness. Any person nominated to witness destruction should have appropriate training and be accountable for this activity directly to the Accountable Officer. An Accountable Officer must not be an authorised witness for the purposes of witnessing the destruction of controlled drugs.

Pharmacists are required to keep records of Schedule 1 and 2 drugs obtained and supplied. Therefore they require an authorised witness to be present for the destruction of these drugs. Pharmacists are therefore not required to keep records of Schedule 3 controlled drugs, unless specifically required to do so in certain circumstances, as described below.

Pharmacists, (and persons conducting a retail pharmacy business), that produce, (i.e. manufacture or compound) Schedule 3 and 4 controlled drugs, are required to keep records relating to this activity. Therefore they must have destruction of these drugs witnessed, as must those persons licensed by the Home Office to produce and supply these items.

Record keeping and therefore destruction requirements for Schedule 3 and 4 controlled drugs also apply to importers, exporters and manufacturers of these drugs.

There are no requirements for the destruction of Schedule 5 controlled drugs to be witnessed by an authorised person, regardless of the activity.

Particulars of the date of destruction and the quantity destroyed must be entered in the register of controlled drugs and signed by the authorised person in whose presence the drug is destroyed. The authorised person may take a sample of the drug which is to be destroyed.

If an authorised witness is required, the pharmacist should make enquiries within their own organisation to determine whether there is an Home Office authorised witness in their superintendent's office or in a senior management position.

Those authorities recently issued by the Home Office licensing section and applying to Public Limited companies operating retail pharmacies (e.g. area managers or superintendent pharmacists that have applied for such authority) and persons in charge of private hospital providing palliative care or hospices wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions will cease at the end of 2007. They should now look to their local Accountable Officer, where appropriate, to ensure they have enough authorised witnesses to maintain safe and effective destruction of controlled drugs.

The Home Office has advised that Schedule 2, 3 and 4 Part I controlled drugs should be destroyed / denatured before being placed into waste containers.

England

In England, the groups of persons who are authorised to witness the destruction of controlled drugs has been extended. An updated list is available from the Department of Health's website at www.dh.gov.uk.

In September 2006, the Department of Health in England issued a direction stating that all those currently authorised to witness destruction of controlled drugs retain that authorisation. In addition, this direction authorised any officer of the healthcare organisation who, for this purpose, is directly accountable to an executive officer of the organisation to witness the destruction of controlled drugs. The new authorised groups could include Strategic Health Authority pharmacy leads, Medical Directors, and clinical governance leads. However, these individuals must be independent of the routine supply and administration of controlled drugs. Accountable Officers designate should not be authorised to witness destruction as one of the criterion for Accountable Officers is their independence from day-to-day management of controlled drugs. Practitioners who are actively involved in the day-to-day management of controlled drugs or, for example, anyone directly involved with GP practices e.g. practice pharmacists who have access to controlled drugs in GP practices, or an individual who is authorised to supply controlled drugs from the GP practice e.g. clinical governance lead working in their own GP practice, should not, be asked to witness the destruction of controlled drugs in that GP practice.

The guidance, which outlines the former list of authorised witnesses, plus the additional groups, can be found at: www.dh.gov.uk/assetRoot/04/13/97/03/04139703.pdf .

Accountable Officers are now able to authorise certain individuals to witness the destruction of controlled drugs. For a list of Accountable Officers in England please refer to: www.healthcarecommission.org.uk/serviceproviderinformation/controlleddrugs/accountableofficers.cfm.

Scotland

In Scotland the list of people currently authorised to witness the destruction of controlled drugs includes:

- Regional Medical Officers of the Scottish Home & Health Department (SHHD);
- Chief Administrative Pharmaceutical Officers;
- Deputy Chief Dental Officer of the SHHD;
- Regional Dental Officers of the SHHD;
- Inspectors of the Royal Pharmaceutical Society of Great Britain;
- Inspectors of the Home Office Drugs Branch;
- Police constables

However, the SHHD was replaced by the Scottish Executive Health Department (SEHD) in 1999 and SEHD does not have Regional Medical Officers or Regional Dental Officers. Also Chief Administrative Pharmaceutical Officers have been replaced. The list has not yet been updated to take account of these changes in terminology and personnel.

Accountable Officers have also been appointed in Scotland and they can authorise certain individuals to witness destruction of CDs. A list of Accountable Officers in Scotland can be found at www.sehd.scot.nhs.uk/mels/CEL2007_03.pdf . Practitioners who are actively involved in the day-to-day management of controlled drugs or, for example, anyone directly involved with GP practices e.g. practice pharmacists who have access to controlled drugs in GP practices, or an individual who is authorised to supply controlled drugs from the GP practice e.g. clinical governance lead working in their own GP practice, should not, be asked to witness the destruction of controlled drugs in that GP practice.

Wales

In Wales, there is currently no definitive list of people authorised to witness the destruction of controlled drugs. Certain individuals are authorised witnesses. Enquiries regarding this should be directed to the office of the Chief Pharmaceutical Officer for Wales.

Patient Returned Controlled Drugs

Patient returned controlled drugs must not be re-used or entered into the controlled drug register and should be destroyed as soon as possible in order to avoid storage problems and an increased security risk.

For now, pharmacists may destroy controlled drugs returned to them by a patient or a patient's representative, from their own homes, without the need for an authorised witness to be present.

See Section 15 - *Standard Operating Procedures*, for new requirements that are now in place in relation to the recording of Schedule 2 controlled drugs returned by patients.

The requirement for safe custody, for certain controlled drugs, applies equally to patient returned controlled drugs. Until such time that patient returned controlled drugs, (that require safe custody), can be destroyed by being denatured and being rendered irretrievable, they too must be kept in the controlled drug cabinet. Patient returned controlled drugs must be kept segregated from stock controlled drugs, and clearly marked as such, to minimise the risk of errors and inadvertent supply.

As the quantity of controlled drugs being returned can often pose a storage problem, as well as an increased security risk, pharmacists are encouraged to destroy patient returned controlled drugs as soon as possible, and not wait for the authorised witness to visit. It is good practice to have the destruction witnessed by another person and to keep a note, not in the controlled drug register, of what was destroyed. Controlled drugs can be placed into waste containers only after the controlled drug has been rendered irretrievable (i.e. by denaturing).

The Home Office has advised that Schedule 2, 3 and 4 Part I controlled drugs should be destroyed / denatured before being placed into waste containers.

England and Wales

Regulations which came into force in England and Wales in July 2005 have placed further controls on waste. Guidance on the Hazardous Waste (England and Wales) Regulations 2005 can be found on the Society's website, at: www.rpsgb.org, and the Environment Agency's website at: www.environment-agency.gov.uk .

Community pharmacists in England and Wales can only accept patient returned medication from patients or individuals, which is classified as household waste. Where a patient has produced waste medicines in their own home, these can be returned to any pharmacy, (which has registered an exemption). The exemption does not restrict who may return the waste medicines from the household to the pharmacy.

Waste from other sources requires a licence or registered exemption.

Additionally, it should be noted that the carriage of waste requires a licence from the Environment Agency.

Community pharmacists would have to determine if the waste to be returned was classified as household waste, or not, before accepting it.

Household waste (including waste medication) that can be accepted back to a community pharmacy is as follows:

Waste from:

- a domestic property;
- a caravan;
- a residential care home providing residential care only (NOT nursing care); or
- a moored vessel used wholly for the purposes of living accommodation.

The Environment Agency has confirmed that the sorting of waste medicines and denaturing (destruction) of controlled drugs returned to a pharmacy from households and by individuals is a "low risk waste activity". The Agency has stated that it does not believe it is in the public

interest to expect pharmacies to obtain a waste management licence for these activities. The Environment Agency, however, emphasises that it may amend or revoke its position at any time and will continue to consider enforcement in all circumstances where an activity has or is likely to cause pollution or harm to health. Pharmacists must ensure that the activities they undertake to denature controlled drugs protect the environment and workers and others within the pharmacy.

Waste from a care home providing nursing care (previously this would have been designated as a nursing home) or returned from a doctor, dentist, vet, midwife or nurse would be classed as industrial waste and would require licences for the storage and treatment (destruction) of that waste from the Environment Agency. Therefore a pharmacy which does not hold such licences, cannot accept this type of waste for destruction and disposal.

The master of a ship or the installation manager of an offshore installation may not destroy any surplus drugs, but must make arrangements to dispose of these items by surrendering it to a constable or contacting the appropriate authority to arrange disposal.

The Secretary of State of a Government Department (for example Home Secretary, Secretary of State for Health) can authorise an individual or a group to witness the destruction of stock controlled drugs. An authorised witness would be required for the destruction of stock controlled drugs. The Home Office is the regulatory authority responsible for enforcing legislation concerning controlled drugs.

The Environment Agency is the regulatory authority for waste legislation. In the case of patient returns, (i.e. waste), in addition to the Home Office, the Environment Agency should be contacted if further advice is required on methods of destruction, (on 08708-506-506).

Scotland

In Scotland, pharmacies should register an exemption under paragraph 39 of Schedule 3 to the Waste Management Licensing Regulations 1994, (as amended), with the Scottish Environment Protection Agency (SEPA). The exemption covers the secure storage of controlled drugs at a pharmacy prior to subsequent collection and disposal. SEPA is willing, at the present time, to accept that the denaturing of controlled drugs forms part of the exempt activity of secure storage. However, SEPA may reconsider this position and pursue enforcement action if the denaturing activity causes, or is likely to cause, pollution of the environment or harm to human health.

Waste regulations, (the Waste Management Licensing Amendment (Scotland) Regulations 2006), that came into force on 1st December 2006 allow pharmacies in Scotland to accept certain waste from care services, including **all** care homes (irrespective of whether or not they employ nurses), subject to certain conditions.

Pharmacies in Scotland can now accept waste controlled drugs from care homes that offer nursing care as well as residential homes without the need for a waste management licence.

"Care services" for the purposes of the above Regulations has the same meaning as in Section 2 of the Regulation of Care (Scotland) Act 2001.

The “care services” from which pharmacies in Scotland may accept returned waste, include the following:

- (a) a support service;
- (b) a care home service;
- (c) a school care accommodation service;
- (d) an independent health care service;
- (e) a nurse agency;
- (f) a child care agency;
- (g) a secure accommodation service;
- (h) an offender accommodation service;
- (i) an adoption service;
- (j) a fostering service;
- (k) an adult placement service;
- (l) child minding;
- (m) day care of children; and
- (n) a housing support service.

For the legal definitions of each type of care service, please refer to subsections 2(2) to 2(27) of the Act, which can be accessed through the Office of Public Sector Information website (www.opsi.gov.uk/legislation/scotland/acts2001/20010008.htm).

Scottish Ministers set up the National Care Standards Committee to develop national standards. Individual standards covering all types of current (or future) registered care settings can be accessed through the Scottish Executive website (www.scotland.gov.uk). The introduction section of each standard gives a fuller description of what is included in each type of care service, for example:

In Scotland, hospices are part of the independent healthcare sector. The hospices have charitable status and make no charge to the users of their services. School care accommodation services are provided for the purpose of the pupil being in attendance at a public, independent or grant-aided school; and consist of the provision, in a place in or outwith the school, of residential accommodation.

Within Scotland, schools are only covered where they come under the definition of a “school care accommodation service”.

Independent hospitals are included in the “independent health care service” definition.

SEPA has advised that an “independent health care service” could potentially include a private doctor’s practice and therefore healthcare wastes from a private (non-NHS) GP’s practice could be returned to a pharmacy. However, waste from an NHS GP practice, cannot be returned to a pharmacy but must be collected by the local NHS Board or their chosen contractors.

There are conditions on the storage of waste, in general, that applies to all waste (including waste controlled drugs), that must be adhered to. For further guidance and information on waste storage conditions, SEPA should be consulted, (on: 01786-457-700).

Methods and Procedures for Destruction

In general, pharmacists are advised to use commercially available controlled drug denaturing kits wherever possible to denature controlled drugs. Pharmacists should ensure that where alternative methods are used to denature controlled drugs, these should protect the environment and workers who might be affected by this activity.

Controlled drugs should be de-blistered and then denatured (preferably using a controlled drug denaturing kit). De-blistering is only permitted by the Environment Agency for controlled drugs, in order to remove the solid dosage form from the loose blister strip or tablet bottle, in order to denature the drug and render it irretrievable.

Fentanyl patches should have the backing removed and the patch folded over onto itself and placed in the waste disposal bin, or preferably a controlled drug denaturing kit.

Ampoules should be opened, the liquid poured into the controlled drug denaturing kit and the ampoule itself be put in the sharps bin. An ampoule that contains powder can have water added to it to dissolve the powder, and the resulting mixture can be poured into the controlled drug denaturing kit.

Aerosol formulations should be expelled into water (to prevent droplets of drug entering the air), and the resultant liquid disposed of as a liquid formulation.

There is a guidance document on the Society's website www.rpsgb.org entitled "Guidance for Pharmacists on the safe destruction of Controlled Drugs, England, Scotland and Wales" which provides further detailed information and advice on the safe methods and precautions to be followed.

17. Midwives

Registered midwives may possess diamorphine, morphine, pethidine and pentazocine in their own right so far as is necessary for the practice of their profession.

Legislation places various controls and conditions on the circumstances under which General Sale List (GSL) medicines, Pharmacy (P) medicines, and Prescription Only Medicines (POMs) can be sold by retail.

These restrictions on the control on retail sale do not apply to: *"the supply or sale (but not offer for sale) of certain medicinal products by a registered midwife in the course of her professional practice"*. The list of certain medicinal products to which this exemption applies includes one controlled drug:

- Pentazocine hydrochloride

This exemption allows a midwife to purchase this controlled drug and to sell or supply it in the course of their professional practice.

Midwives may also administer parenterally, in the course of their professional practice, prescription only medicines containing any of the following controlled drugs:

- Diamorphine
- Morphine
- Pentazocine lactate
- Pethidine hydrochloride

This exemption allows a midwife to purchase these controlled drugs in order to administer them in the course of their professional practice.

Supplies of diamorphine, morphine, pethidine and pentazocine may only be made to a midwife on the authority of a midwife's supply order signed by the "appropriate medical officer" who is a doctor authorised in writing by the local supervising authority, or the person appointed by the local supervising authority to exercise supervision over midwives. The order must specify:

- the name of the midwife;
- the occupation of the midwife
- the purpose for which the controlled drug is required; and
- the total quantity to be obtained.

A midwife is required to keep a record of supplies of diamorphine, morphine and pethidine received and administered in a book used solely for that purpose. She must not destroy surplus stock, but may surrender it to the "appropriate medical officer."

The pharmacist must retain the midwives' supply order for two years. As diamorphine, morphine and pethidine are Schedule 2 controlled drugs, an appropriate entry is required in the controlled drug register. Pentazocine is a Schedule 3 controlled drug and therefore no entry is required in the controlled drug register, although an entry should be made in the prescription only medicine register.

18. Patients Travelling Overseas

Prescribed drugs listed in Schedule 4 Part II (CD Anab POM), (only when in the form of a medicinal product and for administration by a person to himself), and Schedule 5 of the Misuse of Drugs Regulations 2001, as amended, are not subject to import or export licensing.

Pharmacists are advised that patients intending to carry Schedule 2, 3, 4 Part I (CD Benz POM) and 4 Part II (CD Anab POM) drugs abroad, may require a licence (subject to the above exemption for Schedule 4 Part II).

Since the 1st January 2007, the Home Office has issued new guidance for travellers carrying controlled drugs out of the country. It states that:

Only those persons travelling for one month or more and carrying controlled drugs will require a personal licence.

The advice from the Home Office is that, controlled drugs should be:

- carried in original packaging;
- carried in hand luggage;
- carried with a valid personal import / export licence (if travelling for a month or more);

- carried with a letter from the prescribing doctor confirming the carrier's name, destination, drug details and amounts;
- checked with the relevant embassy / consulate to enquire of any restrictions in the country to be visited.

And the Home Office also advises that:

- (a) If a person is staying outside their resident country for a period exceeding three months they are advised to register with a doctor in the country they are visiting for the purpose of receiving further prescriptions.
- (b) Personal licences are normally issued with an expiry date of one week after the expected return date to the UK (or one week after the expected date of departure from the UK in the case of an import licence).
- (c) A personal licence has no legal standing outside the UK and is intended to allow travellers to pass through UK Customs unhindered. Travellers are, therefore, advised to contact the Embassy or Consulate of the country of destination (or any country through which they may be travelling) to check for regulations or restrictions concerning their particular drug(s) before embarking on their journey.

If a personal licence is required, an application form can be downloaded by a patient from the following website: www.drugs.gov.uk. The application form needs to be submitted to the Home Office along with a letter from the prescribing doctor, nurse or drug worker confirming the details.

There is no standard form of letter that should support the application, but it would be advisable that the letter from the appropriate healthcare professional gave details of:

- the patient's name and current address;
- the name, form and strength of the preparation;
- the total quantities of drugs to be carried; and
- the dates of travel to and from the United Kingdom.

Sufficient time should be allowed for processing the application.

Individual doctors who wish to take controlled drugs abroad whilst accompanying patients, may similarly need to be issued with licences. The doctor concerned should contact the Home Office for further details.

Pharmacists are also advised to give the following information to patients wishing to take medicines out of the country:

- In addition to contacting the Embassy / Consulate of the country being entered, and the Home Office, (if necessary);
- Patients should confirm with the Medicines and Healthcare products Regulatory Agency (MHRA) whether the items that they wish to take out of the country require an export licence. Whether one may be required would depend on the individual drug and the quantity involved. The MHRA can be contacted on: 020-7084-2000, or at: info@mhra.gsi.gov.uk ;
- It may also be prudent for patients to contact the carrier (such as the airline company) they are using to determine whether they would require any particular letters of authorisation to be carried or the items to be packaged or stored in any special way.

19. Care Homes, Hospitals and Hospices

A pharmacist may supply Schedule 2, 3, 4 and 5 controlled drug stock items to the person in charge or acting person in charge of an hospital or care home providing nursing care, (which would formerly have been designated as 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.

A pharmacist may supply Schedule 3, 4 and 5 controlled drugs stock items to the person in charge or acting person in charge of other hospitals or care homes providing nursing care, (which would formerly have been designated as nursing homes).

Private hospitals, private care homes providing nursing care, (which would formerly have been designated as nursing homes), and private hospices may only hold stocks of Schedule 2 controlled drugs in accordance with the terms of an Home Office Licence.

A care home providing residential care, (previously designated as a residential home), cannot be supplied with controlled drugs for stock unless they hold an Home Office Licence allowing them to do so.

The Home Office has introduced new arrangements for organisations obtaining licences to store and possess controlled drugs. The pharmacist must ensure that the home requesting the supply has the requisite licence before making the supply of controlled drugs.

For Schedule 2 and 3 controlled drugs, a requisition must also be obtained.

A requisition supplied by a person, (or acting person), in charge of an hospital or care home, (which would formerly have been designated a nursing 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 from an hospital or care home providing nursing care, (which would formerly have been designated a nursing home), for a Schedule 2 or 3 controlled drug be accepted by fax, over the telephone or by any other verbal method.

20. Veterinary Prescriptions

Prescription Requirements

In addition to the requirements listed in Section 5 – *The Supply of Controlled Drugs on Prescription*, (i – ix), for veterinary prescriptions, the following also apply:

- (i) For veterinary prescriptions, the name and address of the person to whom the controlled drug prescribed is to be delivered must be on the prescription.
- (ii) 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 his care.
- (iii) For veterinary prescriptions, the name and address of the owner or keeper and the telephone number of the person prescribing the product is required.

For all the other legal requirements necessary for a veterinary prescription, please see the section on Medicines for Veterinary Use in the Medicines, Ethics and Practice (MEP) guide, at: www.rpsgb.org/pdfs/MEP31s1-8.pdf and the Society's "Guidance on the sale and supply of Veterinary Medicines" at: www.rpsgb.org/pdfs/vetmedsalesupplyguid.pdf .

Veterinary prescriptions **do not** need to be written on a private standardised prescription form and **do not** need to contain the prescriber's identification number and **do not** need to be submitted to the relevant NHS agency as required for human controlled drug prescriptions.

Validity of prescriptions

The validity of controlled drug prescriptions written for animal use is the same as those written for human use, (i.e. 28 days).

It is an offence under legislation for a pharmacist to supply a Schedule 2, 3 or 4 controlled drug before, or later than 28 days after, the appropriate date on the prescription.

The appropriate date, in these circumstances, is defined as:

"the later of the date on which it was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied".

Where a prescriber wishes the 28 day period to start on a date other than the date of signing, the prescriber may specify a start date from which the period will begin. It is possible that the 28 day period may be specified to begin more than 28 days after the date of signing.

With respect to instalment prescriptions, the first supply must be made within 28 days of the appropriate date. The remainder of the instalments must be dispensed only in accordance with the directions on the prescription.

For Schedule 5 controlled drugs, (if the prescription is not repeatable), the prescription cannot be dispensed after six months.

Validity of Owings:

The restriction in legislation, as described above, preventing a pharmacist supplying a Schedule 2, 3 or 4 controlled drug later than 28 days after the appropriate date on the prescription, also applies to owing balances on prescriptions. It has been confirmed by the Home Office that the remainder of a Schedule 2, 3 or 4 controlled drug prescription cannot be supplied after this time period.

It would be advisable for pharmacists to make the person collecting a prescription for an animal aware, that they will not be able to obtain the remainder of a controlled drug prescription after the 28 day time period has elapsed. It would also be advisable that arrangements should be made and procedures put in place to reduce the possibility that a part of the prescription may not be supplied. Where there is a balance owing on a Schedule 2, 3 or 4 controlled drug, the person collecting a prescription for an animal, should be advised at the outset that they must return to collect the remainder of the owing before the 28 day validity lapses.

For Schedule 5 controlled drugs, (as for other non-controlled drug items on a prescription), the balance of an owing cannot be collected more than six months after the appropriate date. If the

prescription is repeatable, and the first dispensing occurred within the six month period, the repeats are legally valid indefinitely, unless the prescriber had stipulated any conditions to the contrary. However, again as above, depending on the time period that had elapsed, the pharmacist would need to make a professional decision whether it was still appropriate to make a supply, or whether it would be necessary to refer back to the prescriber.

Repeats on Veterinary Prescriptions

Repeats for Schedule 2 and 3 controlled drugs are not permitted.

Prescriptions for Schedule 4 controlled drugs may contain repeats. If the prescription is repeatable, the first dispensing must be within 28 days of the appropriate date on the prescription. The prescription cannot be dispensed for the first time after the 28 day period. If the first dispensing occurred within the 28 day period, the repeats are legally valid indefinitely, unless the prescriber had stipulated any conditions to the contrary. Depending on the time period that had elapsed, the pharmacist would need to make a professional decision whether it was still appropriate to make a supply, or whether it would be necessary to refer back to the prescriber.

Prescriptions for Schedule 5 controlled drugs may contain repeats. The first dispensing must be within 6 months of the appropriate date on the prescription. The prescription cannot be dispensed for the first time more than six months after the appropriate date. If the first dispensing occurred within the 6 month period, the repeats are legally valid indefinitely, unless the prescriber had stipulated any conditions to the contrary. Depending on the time period that had elapsed, the pharmacist would need to make a professional decision whether it was still appropriate to make a supply, or whether it would be necessary to refer back to the prescriber.

Prescription Monitoring Arrangements

Veterinary controlled drug prescriptions **must not** be sent away to a relevant NHS agency.

Veterinary controlled drug prescription forms should be preserved by the supplying pharmacy for two years from the date on which the last delivery under it was made.

APPENDIX ONE:

Home Office Drugs Legislation and Enforcement Unit

Prescription and Legislation Enquiries: 020-7035-0464

Licensing Policy Enquiries: 020-7035-0467

Peel Building
6th Floor
2 Marsham Street
London
SW1P 4DF

E-mail: licensing_enquiry.aadu@homeoffice.gsi.gov.uk

Home Office

Switchboard: 0870-000-1585

Home Office
Direct Communications Unit (CCS)
2 Marsham Street
London
SW1P 4DF

General Domestic Licensing Enquiries: 020-7035-0483

Export Enquiries: 020-7035-0484 / 0472

Accountable Officers Details:

In England:

For a list of Accountable Officers in England please refer to:

www.healthcarecommission.org.uk/serviceproviderinformation/controlleddrugs/accountableofficers.cfm .

In Scotland:

For a list of Accountable Officers in Scotland please refer to:

www.sehd.scot.nhs.uk/mels/CEL2007_03.pdf .

APPENDIX TWO:

Guidance and Law and Ethics Bulletins relating to controlled drugs

Changes to the arrangements for dealing with private Controlled Drug prescriptions

Published in the *Pharmaceutical Journal*, September 1, 2007, page 241.

<http://www.pjonline.com/Editorial/20070901/society/ethics.html#1> .

Destruction of schedule 1, 2, 3 and 4 part I Controlled Drugs

Published in the *Pharmaceutical Journal*, August 18, 2007, page 189.

<http://www.pjonline.com/Editorial/20070818/society/ethics.html#2> .

Restriction on OTC pack sizes of analgesics containing codeine or dihydrocodeine

Published in the *Pharmaceutical Journal*, March 31, 2007, page 382.

<http://www.pjonline.com/Editorial/20070331/society/ethics.html#1> .

Methamphetamine: link to cold remedies and reclassification

Published in the *Pharmaceutical Journal*, January 27, 2007, page 114.

<http://www.rpsgb.org/pdfs/LEBmethamphetcoldrem.pdf> .

Missed doses or collections of methadone

Published in the *Pharmaceutical Journal*, January 27, 2007, page 114.

<http://www.rpsgb.org/pdfs/LEBmissedmethadone.pdf> .

Validity period for an owing slip

Published in the *Pharmaceutical Journal*, January 20, 2007, page 90.

<http://www.rpsgb.org/pdfs/LEBvalidperiodowslip.pdf> .

And also Clarification on “Validity period for owing slips”

Published in the *Pharmaceutical Journal*, February 17, 2007, page 200.

<http://www.pjonline.com/Editorial/20070217/society/ethics.html#2> .

Guidance for Pharmacists on the safe destruction of Controlled Drugs, England,

Scotland and Wales The availability of this guidance was announced in the *Pharmaceutical Journal*, on January 6, 2007. Available as a guidance document on the Society’s website at:

<http://www.rpsgb.org/pdfs/cdsafedestructionguid.pdf> .

Approved wording on instalment prescriptions to cover pharmacy closures

Published in the *Pharmaceutical Journal*, December 23 / 30, 2006, page 774.

<http://www.rpsgb.org/pdfs/LEBapprovwordinginstalprescs.pdf> .

Methadone Oral Solution

Published in the *Pharmaceutical Journal*, November 25, 2006, page 651.

<http://www.rpsgb.org/pdfs/LEBmethadoneoralsol.pdf> .

Licence requirements for the prescribing of cocaine, diamorphine and dipipanone for addiction

Published in the *Pharmaceutical Journal*, November 4, 2006, page 558.
<http://www.rpsgb.org/pdfs/LEBcocainediamorphdipip.pdf> .

Technical errors on Schedule 2 and 3 Controlled Drug prescriptions
Published in the *Pharmaceutical Journal*, September 23, 2006, page 377.
<http://www.pjonline.com/Editorial/20060923/society/ethics.html#1> .

Further changes to the Misuse of Drugs Regulations 2001
Published in the *Pharmaceutical Journal*, September 9, 2006, page 322. Available as a guidance document on the Society's website at:
<http://www.pjonline.com/Editorial/20060909/society/ethics.html> .

Changes in the management of CDs affecting pharmacists England, Scotland and Wales (June 2006) Published in the *Pharmaceutical Journal*, July 1, 2006, pages 25 - 29.
Available as an updated guidance document on the Society's website at:
<http://www.rpsgb.org/pdfs/cdmanagechguid.pdf> .

Extemporaneous preparation of methadone mixture
Published in the *Pharmaceutical Journal*, February 25, 2006, page 245.
<http://www.pjonline.com/Editorial/20060225/society/ethics.html#1> .

Ketamine becomes a Class C Controlled Drug
Published in the *Pharmaceutical Journal*, January 7, 2006, page 21.
<http://www.pjonline.com/Editorial/20060107/society/ethics.html#1> .

Amendments to the Misuse of Drugs Regulations: guidance for pharmacists
Published in the *Pharmaceutical Journal*, November 12, 2005, page 617.
<http://www.pjonline.com/Editorial/20051112/society/ethics.html#1> .

Date-expired Controlled Drugs stock
Published in the *Pharmaceutical Journal*, August 27, 2005, page 268.
<http://www.pjonline.com/Editorial/20050827/society/ethics.html#2> .

Supply of extemporaneously prepared products containing Schedule 5 Controlled Drugs
Published in the *Pharmaceutical Journal*, August 25, 2005, page 268.
<http://www.pjonline.com/Editorial/20050827/society/ethics.html#1> .

Instalment dispensing of Controlled Drugs
Published in the *Pharmaceutical Journal*, July 23, 2005, page 122.
<http://www.pjonline.com/Editorial/20050723/society/ethics.html#1> .

Instalment dispensing of diazepam on FP10(MDA)
Published in the *Pharmaceutical Journal*, June 18, 2005, page 775.
<http://www.pjonline.com/Editorial/20050618/society/ethics.html#3> .

Changes to Misuse of Drugs Regulations
Published in the *Pharmaceutical Journal*, June 28, 2003, page 910.
<http://www.pjonline.com/Editorial/20030628/society/ethics.html#1> .

Supervision of CDs within the pharmacy
Published in the *Pharmaceutical Journal*, June 1, 2002, page 789.
<http://www.pjonline.com/Editorial/20020601/society/ethics.html#2> .

Safe storage of methadone in the home

Published in the *Pharmaceutical Journal*, March 23, 2002, page 414.

<http://www.pjonline.com/Editorial/20020323/society/ethics.html#1> .

Instalment dispensing of buprenorphine

Published in the *Pharmaceutical Journal*, March 16, 2002, page 380.

<http://www.pjonline.com/Editorial/20020316/society/ethics.html#2> .

The Misuse of Drugs Regulations 2001

Published in the *Pharmaceutical Journal*, January 26, 2002, page 115.

<http://www.pjonline.com/Editorial/20020126/society/ethics.html> .

Over-Packaging of Controlled Drugs

Published in the *Pharmaceutical Journal*, March 3, 2001, page 279.

<http://www.pjonline.com/Editorial/20010303/society/ethics.html#2> .

Hydromorphone record-keeping

Published in the *Pharmaceutical Journal*, September 2, 2000, page 327.

http://www.pjonline.com/Editorial/20000902/society/law_hydromorphone.html .

Substitution of colourless and / or sugar-free methadone mixture on prescriptions.

Published in the *Pharmaceutical Journal*, August 28, 1999, page 308.