



Royal  
Pharmaceutical  
Society  
of Great Britain

## **Changes in the management of controlled drugs affecting pharmacy**

### **England , Scotland and Wales**

#### **Introduction:**

A number of changes to the monitoring and inspection, prescribing, dispensing, record keeping and destruction of controlled drugs (CDs) are being introduced as part of the Government's ongoing programme of work to strengthen the governance arrangements for the management and use of CDs. These are a mixture of legislative requirements and professional good practice guidance.

The Misuse of Drugs Regulations 2001 were subject to amendment in 2006. Changes that were made included the following:

- the introduction of a requirement for private prescriptions for human use for certain controlled drugs to be dispensed in community to be written on a standardised form and contain a prescriber's identification number;
- the introduction of a requirement to send copies or originals (dependent on the country in question) of private controlled drug prescriptions to a central NHS agency;
- the reduction in the validity period of prescriptions for certain Schedules of controlled drugs;
- the introduction of a requirement for pharmacists to ascertain the identity of the person collecting a Schedule 2 controlled drug; and
- the introduction of a facility by which pharmacists are permitted to make certain minor technical amendments to controlled prescriptions under certain circumstances.

Further changes are expected in 2007. These changes relate to England, Scotland and Wales, however, the arrangements for meeting the new requirements may differ between each of the countries.

The Controlled Drugs (Supervision of Management and Use) Regulations 2006, which relate to England and Scotland only, introduced a number of changes including:

- the requirement for designated bodies (as defined in the 2006 Regulations) to appoint an Accountable Officer, who would be responsible for the management and use of controlled drugs within their area;
- duties of co-operation on responsible bodies; and
- periodic inspection of premises.

Wales are writing their own regulations to support the Health Act 2006 and the systems and timing of implementation may be different.

Northern Ireland sets its own regulations as far as the misuse of drugs is concerned.

**Purpose of the guidance:**

To set out the current position in relation to the controls on the supervision and management of CDs and how they apply to England, Scotland and Wales.

To identify forthcoming anticipated changes and when they are expected to happen.

To differentiate between legislative and good practice requirements.

**Table one: Changes for NHS and Private Prescriptions:**

Change	Status	When	England	Scotland	Wales	Comments
<p>1a) Handwriting requirements for Schedule 2 and 3 controlled drug prescriptions have been removed.</p> <p><i>* Permissive means that an action is legally allowed to be carried out but there is not a mandatory requirement to do so e.g. controlled drug prescriptions <b>can be</b> computer generated but <b>do not have to be</b> computer generated.</i></p>	Legal	Nov 2005	Permissive*	Permissive*	Permissive*	<p>Prescribers can issue computer-generated prescriptions for all controlled drugs.</p> <p>Only the signature has to be in the prescriber's own handwriting.</p> <p>However, there is not presently a mandatory requirement to issue computer-generated controlled drug prescriptions.</p>
<p>1b) The validity of Schedule 2, 3 and 4 controlled drug prescriptions has been restricted to 28 days from the appropriate date on the prescription.</p>	Legal	7 <sup>th</sup> July 2006	Requirement	Requirement	Requirement	<p>This means that the prescription must not be dispensed if more than 28 days have elapsed since the appropriate date.</p> <p>The 28 day validity applies to any supply made against a prescription. Balances of owings cannot be supplied more than 28 days after the appropriate date on a controlled drug prescription either. The appropriate date will either be the date the prescription was signed by the person issuing it or the date indicated by him/her as being the start date.</p>

<p>1c) Standardised private prescription forms will be required to be used for the private prescribing of all Schedule 2 and 3 controlled drugs for human use that will be dispensed in community pharmacies / dispensing practices.</p>	<p>Legal</p>	<p>7<sup>th</sup> July 2006 for England &amp; Scotland. 1<sup>st</sup> January 2007 for Wales.</p>	<p>Requirement</p> <p>In England these are called FP10 (PCD).</p>	<p>Requirement</p> <p>In Scotland these are called PPCD(1).</p>	<p>Requirement</p> <p>In Wales these are called WP10PCD and WP10PCDSS.</p>	<p>Community pharmacists can only dispense a private prescription for a Schedule 2 or 3 controlled drug for human use if it is on the relevant standardised private prescription form.</p> <p>The requirement to use the standardised forms when prescribing Schedule 2 &amp; 3 controlled drugs applies to:</p> <p>(a) private prescriptions issued by doctors, dentists and non-medical prescribers (e.g. supplementary prescribers, nurse independent prescribers, and when they are able to prescribe controlled drugs - pharmacist independent prescribers).</p> <p>(b) hospital prescriptions issued to private patients by a hospital prescriber which are to be dispensed by a community pharmacy.</p> <p>This requirement does not apply:</p> <p>(a) to private prescriptions which will be dispensed in an hospital pharmacy.</p> <p>(b) to veterinary prescriptions.</p> <p>(c) where prescriptions for prisoners and some other patients are provided by the NHS under a service level agreement, (in England and Wales), – this is classed as NHS activity and the new private prescription forms for controlled drugs should <b>not</b> be used for such patients.</p>
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<p>1d) <b>Private</b> prescriptions for all Schedule 2 &amp; 3 controlled drugs for human use are required to contain the prescriber identification number**.</p> <p><i>**The prescriber identification number means the number issued by the relevant NHS Agency for the purposes of that person's private prescribing. It is not the prescriber's professional registration number</i></p>	Legal	7 <sup>th</sup> July 2006 for England & Scotland. 1 <sup>st</sup> January 2007 for Wales.	Requirement  Private prescribers will be issued with a new six-digit identifier starting with the number 6 if writing prescriptions to be dispensed in the community.	Requirement  Valid NHS prescriber codes will be used where available. New private prescriber codes will be issued where necessary.	Requirement  Unique prescriber identification codes will be issued for all private prescribers of Schedule 2 and 3 controlled drugs	<p>Community pharmacists are only able to dispense a <b>private</b> prescription for a Schedule 2 or 3 controlled drug for human use issue if it contains the prescriber's identification number.</p> <p>Private prescribers should inform their Primary Care Organisation, (PCO), if they need a private prescriber identification number.</p> <p>Pharmacists in a hospital are able to make a supply against a private controlled drug prescription if it does not specify the prescriber's identification number.</p>
<p>1e) Pending legislative changes a copy of the prescription for Schedule 2 and 3 controlled drugs are required to be sent to the NHS Business Services Authority (NHSBSA), NHS National Services Scotland and Health Solutions Wales at the end of each month for collection and analysis purposes.</p>	Legal	7 <sup>th</sup> July 2006. This requirement has applied to England Scotland & Wales from 7 <sup>th</sup> July 2006.	Requirement	Requirement	Requirement  Following the last day of the month, copies of WP10PCD and WP10PCDSS prescriptions are to be sent to Health Solution Wales in a separate bundle to NHS prescriptions.	<p>Pending proposed changes to The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, as amended, pharmacists are required to retain originals of all private prescriptions for 2 years from the date of dispensing.</p> <p>In Scotland, pharmacists have been asked to submit the original private prescription for Schedule 2 or 3 controlled drugs because of the way in which prescriptions are processed by the PSD.</p> <p>The requirement does not apply to veterinary prescriptions.</p>

<p>1f) Pharmacists must ascertain whether the person collecting a Schedule 2 controlled drug is the patient, the patient's representative or a healthcare professional acting in their professional capacity on behalf of the patient.</p>	<p>Legal</p>	<p>7<sup>th</sup> July 2006</p>	<p>Requirement</p>	<p>Requirement</p>	<p>Requirement</p>	<p>If the person collecting the Schedule 2 controlled drug is the patient or the patient's representative the pharmacist may ask for proof of identity.</p> <p>If the person is a healthcare professional acting in his professional capacity on behalf of the patient, the pharmacist must obtain the person's name and address and must ask for proof of identity unless the health professional is known to them.</p> <p><i>See box 1 for further information</i></p>
<p>1g) Prescription forms (private and NHS) contain a space on the back of the prescription for those collecting Schedule 2 or 3 controlled drugs for human use to confirm that they have done so.</p>	<p>Good practice</p>	<p>Summer 2006</p>	<p>Good practice</p> <p>New prescription forms have been issued in England from March 2006.</p>	<p>Good practice</p> <p>New prescription forms have been issued in Scotland from June 2006.</p>	<p>Good practice</p> <p>This space will currently only be available on private controlled drug prescriptions.</p>	<p>In England and Scotland, this declaration appears on both NHS and non-NHS (private) forms and in Wales it currently only appears on non-NHS (private) forms.</p> <p>Pharmacists have discretion whether or not to supply if the collector does not sign the back of the prescription.</p>

<p>1h) The quantity of Schedule 2, 3, and 4 controlled drugs to be prescribed at any one time should not exceed 30 days supply.</p>	<p>Good practice</p>	<p>Current requirement</p>	<p>Good Practice</p>	<p>Good Practice</p>	<p>Good Practice</p>	<p>In circumstances where the prescriber believes that a supply of more than 30 days is clinically indicated and would not pose an unacceptable risk to patient safety, the prescriber should make a record of the reasons in the patient's notes and should be ready to justify this decision if required.</p> <p>This is good practice, not a legal requirement because there may be circumstances where there is a genuine need to prescribe more than 30 days supply.</p> <p>Pharmacists are able to dispense Schedule 2, 3 &amp; 4 controlled drug prescriptions calling for more than 30 days supply.</p>
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1i) Prescribers should not prescribe or administer controlled drugs for themselves, or for close family or friends, except in an emergency.	Good practice	Current requirement	Good Practice	Good Practice	Good Practice	<p>Each professional regulatory body will have its own guidance which should be referred to.</p> <p>The GMC advises that doctors should not prescribe a controlled drug for themselves or someone close to them unless there is no other person with the legal right to prescribe available to assess the patient's clinical condition and to delay prescribing would put the patient's life or health at risk, or cause the patient unacceptable pain.</p> <p>The treatment should be immediately necessary to:</p> <ul style="list-style-type: none"> <li>• Save life</li> <li>• Avoid significant deterioration in the patient's health, or</li> <li>• Alleviate otherwise uncontrollable pain</li> </ul>
1j) Prescribers should, where possible, include the <b>patient's identifier</b> on all controlled drug prescriptions.	Good practice	Summer 2006	<p>Good practice</p> <p>In England this is the patient's NHS number.</p>	<p>Good practice</p> <p>In Scotland this is the Community Health Index (CHI) number.</p>	<p>Good practice</p> <p>Arrangements yet to be made in Wales.</p>	<p>This is currently recommended good practice but is likely to become a mandatory requirement in due course.</p>

\* Permissive means that an action is legally allowed to be carried out but there is not a mandatory requirement to do so e.g. controlled drug prescriptions **can be** computer generated but **do not have to be** computer generated.

\*\*The prescriber identification number means the number issued by the relevant NHS Agency for the purposes of that person's private prescribing. It is not the prescriber's professional registration number

**Table two: Changes in record keeping:**

Change	Status	When	England	Scotland	Wales	Comments
<p>2a) Controlled drug registers can be kept electronically.</p> <p><i>* Permissive means that an action is legally allowed to be carried out but there is not a mandatory requirement to do so e.g. controlled drug prescriptions <b>can be</b> computer generated but <b>do not have to be</b> computer generated.</i></p>	Legal	Nov 2005	Permissive*	Permissive*	Permissive*	<p>Controlled drug registers can be kept electronically as long as they comply with the legislation.  <a href="http://www.pionline.com/Editorial/20051112/society/ethics.html">www.pionline.com/Editorial/20051112/society/ethics.html</a>.</p> <p>There is no mandatory requirement to maintain an electronic controlled drug register at this time.</p>
<p>2b) The controlled drug register can be used to record additional information to that required or allowed under the provisions of the Misuse of Drugs Regulations.</p> <p><i>* Permissive means that an action is legally allowed to be carried out but there is not a mandatory requirement to do so e.g. controlled drug prescriptions <b>can be</b> computer generated but <b>do not have to be</b> computer generated.</i></p>	Legal	7 <sup>th</sup> July 2006	Permissive*	Permissive*	Permissive*	<p>The record keeping requirements specified in the Misuse of Drugs Regulations are the minimum fields of information that must be recorded. Pharmacists may record additional information in the controlled drug register, e.g. running balances. The Home Office consultation on the review of the form of the controlled drug register is currently being undertaken, with an expected implementation date of August 2007</p>
<p>2c) All controlled drug registers should contain a running balance.</p>	Good practice	Current requirement	Good practice	Good practice	Good practice	<p>National guidance is available at <a href="http://www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf">www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf</a></p> <p>This is expected to become a mandatory requirement once electronic registers are in common use.</p>

2d) Records should be made for all patient returned Schedule 2 controlled drugs.	Good practice	Current requirement	Good practice	Good practice	Good practice	<p>It is good practice for pharmacists (and doctors) to keep a record of controlled drugs returned by patients.</p> <p>The Society produces forms, which are available on the Society's website, (at: <a href="http://www.rpsgb.org.uk/pdfs/restooldestrcd.pdf">www.rpsgb.org.uk/pdfs/restooldestrcd.pdf</a>), to record these details.</p> <p>Alternatively, various bodies and companies can supply a book to record Patient Returns.</p> <p>Records of these patient returns should be kept for a period of at least seven years.</p> <p>It is a legal requirement for a Standard Operating Procedure to be in place covering the maintaining of records of Schedule 2 controlled drugs returned by patients, in England since 1<sup>st</sup> January 2007, in Scotland since 1<sup>st</sup> March 2007 and in Wales from a date yet to be finalised.</p>
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**Table three: Inspection and Monitoring**

Change	Status	When	England	Scotland	Wales	Comments
<p>3a) Designated bodies are required to appoint an Accountable Officer.</p> <p>Designated bodies are, for example:</p> <p>(a) a Primary Care Trust (PCT);</p> <p>(b) a Health Board (HB);</p> <p>(c) an NHS trust;</p> <p>(d) an NHS foundation trust;</p> <p>(e) an English or Scottish independent hospital; and</p> <p>(f) the following Special Health Boards:</p> <p style="padding-left: 20px;">(i) the Scottish Ambulance Service Board,</p> <p style="padding-left: 20px;">(ii) the National Waiting Times Centre Board,</p> <p>and</p> <p style="padding-left: 20px;">(iii) the State Hospitals Board for Scotland.</p>	Legal	In England, since 1 <sup>st</sup> January 2007. In Scotland, from 1 <sup>st</sup> March 2007. In Wales, from date yet to be finalised.	Requirement From 1 <sup>st</sup> January 2007.	Requirement From 1 <sup>st</sup> July 2007.	Requirement From date yet to be confirmed.	<p>The duty to appoint an Accountable Officer is contained in the Health Bill and supported by accompanying regulations, (The Controlled Drugs (Supervision of Management and Use) Regulations 2006.</p> <p>Currently the legislation only applies in England and Scotland.</p> <p>The legislation will apply to the whole of the UK, though Wales and Northern Ireland can write their own regulations to apply the system differently in their own administrations.</p>

<p>3b) All healthcare providers who hold a stock of controlled drugs on the premises, which includes community pharmacies, will be expected to have, and comply with, an adequate and up to date Standard Operating Procedure (SOP), which must cover:</p> <p>(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(a) (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.</p>	<p>Legal</p>	<p>In England, since 1<sup>st</sup> January 2007. In Scotland, since 1<sup>st</sup> March 2007. In Wales, from date yet to be finalised.</p>	<p>Requirement</p>	<p>Requirement</p>	<p>Requirement</p> <p>From date yet to be confirmed.</p>	<p>The Department of Health has issued further guidance on writing adequate Standard Operating Procedures.</p> <p>The guidance can be viewed at:  <a href="http://www.dh.gov.uk/assetRoot/04/14/25/63/04142563.pdf">www.dh.gov.uk/assetRoot/04/14/25/63/04142563.pdf</a>.</p> <p>The Scottish Executive Health Department and Department for Health and Social Services will be issuing further guidance for SOPs and what should be included in them in Scotland and Wales respectively.</p>
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3c) RPSGB inspectors will be under a statutory duty to co-operate with other responsible bodies and may share information relating to CDs, where there are concerns.	Legal	In England, since 1 <sup>st</sup> January 2007. In Scotland, since 1 <sup>st</sup> March 2007. In Wales, from date yet to be finalised.	Requirement	Requirement	Requirement From date yet to be confirmed.	Responsible bodies include all regulators, the police, PCTs, HBs, Trusts, Healthcare Commission, local authorities and Scottish and English independent hospitals.
3d) Periodic declarations and self assessments may be requested from medical practitioners on medical performers' lists (in England) and primary medical services performers' list (in Scotland), NHS Trusts, Foundation Trusts, persons registered with the Healthcare Commission, English care homes and registered pharmacies.	Legal	In England, since 1 <sup>st</sup> January 2007. In Scotland likely start date is 1 <sup>st</sup> July 2007. In Wales, from date yet to be finalised.	Requirement	Requirement	Detailed mechanism is still being discussed in Wales.	In England (and Scotland from July 2007) the Society will require community pharmacy owners to complete periodic declarations for submission to the RPSGB and these together with pre-inspection visit self-assessment forms will be used to inform monitoring and inspection visits by RPSGB inspectors.
3e) Each primary care provider in contract with a PCT or HB will undergo periodic inspections in relation to controlled drugs. For community pharmacies (Scotland and Wales) these inspections will be undertaken by RPSGB inspectors.	Legal	In England, since 1 <sup>st</sup> January 2007. In Scotland, likely start date is 1 <sup>st</sup> July 2007. In Wales, from date yet to be finalised.	Periodic inspections undertaken by RPSGB inspectors	Periodic inspections will be undertaken by RPSGB inspectors from July 2007	Arrangement yet to be made in Wales.	This will involve reviewing benchmark analysis derived from existing information, the provider's self assessment of their clinical standards in prescribing, administering, storage and disposal of controlled drugs, and a statement that they comply with the Misuse of Drugs Act and associated regulations.

<p>3f) RPSGB inspectors will be incorporating controlled drug monitoring and inspection within their routine visits.</p>	<p>Good practice</p>	<p>In England, since 1<sup>st</sup> January 2007. In Scotland, likely start date 1<sup>st</sup> July 2007. In Wales, there is currently no agreement in place for the RPSGB inspectors to undertake the CD inspections in community pharmacies.</p>	<p>Agreement</p>	<p>Agreement</p>	<p>Under discussion.</p>	<p>This is an agreement between RPSGB and the relevant Government bodies in each country, where appropriate. Further information on the role of the RPSGB inspectors. In controlled drug monitoring and inspection is available on the Society website <a href="http://www.rpsgb.org">www.rpsgb.org</a></p>
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**Table four: Additional changes**

Change	Status	When	England	Scotland	Wales	Comments
<p>4a) Pharmacists will be able to supply Schedule 2 and 3 controlled drugs except temazepam, against some prescriptions that have a minor technical error but where the prescriber's intention is clear (<i>see box 2 below</i>).</p> <p><i>N.B. The controlled drug prescription requirements (e.g. total quantity to be stated in words and figures) apply to all Schedule 2 and 3 controlled drugs except temazepam which is why temazepam is excluded from this change.</i></p>	Legal	7 <sup>th</sup> July 2006	Permissive	Permissive	Permissive	<p>Pharmacists will be able to amend a controlled drug prescription where there are minor typographical errors, spelling mistakes or where the total quantity 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.</p> <p>Pharmacists will have to exercise all due diligence and be satisfied on reasonable grounds that the prescription is genuine and that they are supplying in accordance with the instructions of the prescriber.</p> <p>The pharmacist will need to amend the prescription in ink or otherwise indelibly and mark the prescription so that the amendment is attributable to them.</p>

<p>4b) The number and groups of people who are authorised to witness the destruction of controlled drugs will be extended.</p>	<p>Authorisation by a department of state</p>	<p>2006 / 2007</p>	<p>Permissive</p>	<p>Under discussion</p>	<p>Under discussion</p>	<p>In England, the groups of people who are authorised to witness the destruction of CDs has been extended. <b>In addition</b> to those already authorised, authorisation has been extended to any officer of a healthcare organisation who is directly accountable to an executive officer of that organisation and could include SHA pharmacy leads, medical directors and clinical governance leads.</p> <p>In Scotland and England, the Accountable Officer will be able to authorise people to witness the destruction of controlled drugs within their organisational areas as long as that person is subject to a professional code of ethics and / or has been the subject of CRB checks and have appropriate training. The authorised person should be independent of day to day use of the management of controlled drugs.</p> <p>When the Regulations under the Health Act come into force in Wales, further arrangements will be made.</p> <p>There are proposals currently subject to a Home Office consultation regarding whether an Accountable Officer will be able to authorise persons to act as witnesses for the destruction of controlled drugs. The expected implementation date for any such change is August 2007.</p>
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4c) Accountable Officers within PCTs and HBs will have a responsibility for ensuring that safe systems are in place for the safe disposal of "patient-returned" controlled drugs	Legal	In England, since 1 <sup>st</sup> January 2007. In Scotland, since 1 <sup>st</sup> March 2007. In Wales, from date yet to be finalised.	Requirement of the Accountable Officer.	Requirement of the Accountable Officer.  (Who must be in place from 1 <sup>st</sup> July 2007)	Arrangement yet to be made in Wales.	Ideally, patient returned controlled drugs should be taken to a pharmacy for destruction.
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## **BOX 1**

### **Proof of identity**

From 7<sup>th</sup> July 2006 pharmacists must ascertain the role of anyone collecting a Schedule 2 controlled drug supplied against a prescription. They must ascertain whether the person is the patient, the patient's representative or a healthcare professional acting within their professional capacity on behalf of the patient.

In order to ensure that patients have access to the drugs that they require, a pharmacist is able to supply a Schedule 2 controlled drug without proof of identity. Even when the pharmacist does not know that person, it will **not** be a criminal offence to make such a supply without proof of identity,.

### **Patient or patient's representative:**

If the person collecting the Schedule 2 controlled drug is the patient or the patient's representative the pharmacist may request evidence of that person's identity and may refuse to supply the controlled drug if they are not satisfied as to the identity of the person. This means that pharmacists will have the 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 that the person collecting is who they say they are.

Circumstances where ID may not be required includes when the person collecting the controlled drug is known to the pharmacist (the patient, close relative or friend of the patient) or when the pharmacist feels that asking for ID may compromise patient confidentiality.

### **Healthcare professional:**

If the person collecting the Schedule 2 controlled drug is a healthcare professional acting in their professional capacity on behalf of the patient, the pharmacist must obtain the name and address of the healthcare professional and, unless they are already acquainted with that person, they must request evidence of that person's identity. However, even if ID is not provided the pharmacist may still supply the controlled drug.

### **Types of ID:**

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.

### **Record keeping:**

The amendments to the Misuse of Drugs Regulations 2001 outline record keeping requirements for the identity of persons collecting schedule 2 controlled drugs to take effect from January 2008. However, the Society is aware that the Home Office is currently undertaking a consultation reviewing the form of the controlled drug register. Further guidance on record keeping will be issued in due course.

## **BOX 2**

### **Technical errors**

From 7<sup>th</sup> July 2006 pharmacists may make certain amendments to Schedule 2 and 3 controlled drug prescriptions except temazepam\* provided that:

- having exercised all due diligence the pharmacist is satisfied on reasonable grounds that the prescription is genuine
- having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that they are supplying the controlled drug in accordance with the intention of the prescriber
- 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 Misuse of Drugs controlled drug prescription requirements as the case may be; and
- the pharmacist marks the prescription so that the amendment they have made is attributable to them

The only errors that pharmacists can currently amend are minor typographical errors or spelling mistakes or 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. they can add the words or the figures to the controlled drug prescription if they have been omitted.

*\* The controlled drug prescription requirements (e.g. requirement for total quantity to be expressed in words and figures) apply to all Schedule 2 and 3 controlled drugs except temazepam which is why temazepam is excluded from this change.*

## **Who can currently prescribe / supply / administer Controlled Drugs?**

Currently doctors, dentists and veterinary practitioners can prescribe all controlled drugs in Schedules 2 to 5. Doctors are only able to prescribe diamorphine, dipipanone or cocaine to substance misusers for the treatment of addiction if they hold a licence issued by the Home Office. All doctors can prescribe such drugs for patients, including substance misusers, for relief of pain due to organic disease or injury, without a specific licence.

### ***Independent Non-Medical Prescribers:***

Nurse independent prescribers (formerly extended formulary nurse prescribers) can prescribe, administer and 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.

There is currently a consultation being undertaken to extend the list of items and the circumstances under which nurse independent prescribers can prescribe, supply and administer controlled drugs. Therefore the above list may soon be subject to change.

Pharmacist independent prescribers cannot currently prescribe any controlled drugs. There is a current consultation being undertaken to allow pharmacist independent prescribers to prescribe controlled drugs.

For the most up to date guidance the Society's website, at: [www.rpsgb.org](http://www.rpsgb.org) should be consulted.

### ***Supplementary Non-Medical Prescribers:***

Supplementary nurse and pharmacist prescribers can prescribe and administer any controlled drug as long as it is within the Clinical Management Plan specific to that

patient and agreed between the independent prescriber, the supplementary prescriber and the patient.

Chiropodists, podiatrists, physiotherapists, radiographers and optometrists who are supplementary prescribers are also able to prescribe controlled drugs, in partnership with a doctor and according to a patient's Clinical Management Plan.

**Midwives:**

Midwives can possess, supply and administer diamorphine, morphine, pethidine and pentazocine, provided it is in the course of their professional midwifery practice.

A Midwives Supply Order is required for any controlled drug that a midwife is lawfully entitled to supply and administer in accordance with the Prescription Only Medicines (Human Use) Order 1997, as amended.

**Patient Group Directions:**

The following controlled drugs can be supplied and administered under Patient Group Directions (PGDs):

- Diamorphine, but only for the treatment of cardiac pain by nurses working in coronary care units or hospital accident and emergency departments;
- All drugs listed in Schedule 4 of the Regulations except anabolic steroids and injectable formulations for the purpose of treating a person who is addicted to a drug;
- All drugs listed in Schedule 5 of the Regulations.

Occupational therapists, orthotists and prosthetists have been able to supply and administer controlled drugs in Schedule 4 and 5 (except anabolic steroids) under a PGD since 7<sup>th</sup> July 2006.

There is currently a consultation being undertaken to extend the list of items and the circumstances under which controlled drugs can be included in PGDs. Therefore the above list may soon be subject to change.

For the most up to date guidance the Society's website, at: [www.rpsgb.org](http://www.rpsgb.org) should be consulted.

**Administration:**

Any person, other than a doctor or dentist, may administer to a patient in accordance with the directions of a doctor or dentist, any drug specified in Schedules 2, 3 or 4.

Any person can administer any controlled drug in accordance with the directions of a supplementary prescriber acting under and in accordance with the terms of a Clinical Management Plan.

Any person may administer to another any drug in Schedule 5.

## **Destruction of Controlled Drugs**

### **Patient Returned Controlled Drugs**

Currently, a pharmacist, (or a practitioner), may destroy controlled drugs returned to him by a patient or a patient's representative, from their own homes, without the presence of a person who is an authorised witness. Such controlled drugs must not be returned to stock.

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 rendered irretrievable, they 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.

The destruction of patient returned controlled drugs is classified as waste treatment, and would normally require a waste management licence. Stock controlled drugs are not regarded as waste until they are destroyed so there is no requirement for a waste management licence.

It is good practice for pharmacists to keep a record of controlled drugs returned by patients. It is a legal requirement that Standard Operating Procedures cover the maintaining of records of Schedule 2 patient returned drugs.

### **England and Wales**

The Environment Agency is the regulatory authority for the waste legislation in England and Wales, although the Welsh Assembly Government also issues their own regulations regarding waste disposal, and it has acknowledged that certain activities undertaken in pharmacy are 'low risk'. Having considered the risks posed by the destruction of controlled drugs at a pharmacy, the Agency has decided that it does not believe it is in the public interest to expect pharmacies to obtain a waste management licence for the destruction of patient returned controlled drugs. However, the Environment Agency will keep the matter under review and may amend or revoke its position at any time. Therefore, pharmacists should ensure that denaturing is undertaken in a way that does not harm the environment or pose a risk to staff.

Controlled drugs returned by patients from their own homes and residential homes, can be sorted, popped from blister packaging and denatured in the pharmacy. Ideally, controlled drug denaturing kits should be used, but where alternative methods are adopted, these should safeguard the environment and the health of workers and other members of the public. The methods that can be used for

denaturing controlled drugs are outlined in “Guidance for pharmacists on the safe destruction of controlled drugs”, which is available as a separate guidance document on the Society’s website: [www.rpsgb.org/pdfs/cdsafedestructionguid.pdf](http://www.rpsgb.org/pdfs/cdsafedestructionguid.pdf) .

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 patients in care homes providing residential care only is also classified as household waste and may be returned to a pharmacy with an exemption.

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.

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 Environment Agency is the regulatory authority for waste legislation in England and Wales and can be contacted on 08708-506-506.

### Scotland

Waste regulations, (the Waste Management Licensing Amendment (Scotland) Regulations 2006), that came into force on 1<sup>st</sup> 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.

Care services are defined as care home services that provide accommodation, together with nursing, personal care or personal support, for persons by reason of their vulnerability or need. Care services do not include hospitals, public, independent or grant-aided schools, independent health care services or other services specifically excluded by the Regulations.

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.

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, the Scottish Environment Protection Agency (SEPA) is the regulatory authority for the waste legislation in Scotland, and can be contacted on: 01786-457-700.

## 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,.

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, (and persons conducting a retail pharmacy business), that produce, (i.e. manufacture or compound) Schedule 3 or 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.

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.

**In England**, the groups of people who are authorised to witness the destruction of controlled drugs has been expanded under authorisation by a department of state. In addition to the current list any officer of a healthcare organisation who, for this purpose, is directly accountable to an executive officer of the organisation is authorised to witness the destruction of controlled drugs. This may include Strategic Health Authority pharmacy leads, Medical Directors and clinical governance leads.

The current of list of authorised witnesses for England is available at [http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/PrimaryCare/PrimaryCareArticle/fs/en?CONTENT\\_ID=4125202&chk=yB3Of5](http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/PrimaryCare/PrimaryCareArticle/fs/en?CONTENT_ID=4125202&chk=yB3Of5)

**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.

**In Scotland** the list of people currently authorised to witness the destruction of CDs 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 no longer has certain posts listed above. The list has not been updated to take account of these changes in terminology and personnel.

## **Changes still to come**

The Government's response to the Fourth report of The Shipman Inquiry outlined a number of further changes to the management of controlled drugs. These changes are expected to occur sometime in the future, and further guidance will be provided when required.

- The list of controlled drugs that can be included in a PGD is set to be extended. The circumstances in which controlled drugs will be able to be included in a PGD are also due to be expanded.
- Pharmacist independent prescribers will be able to prescribe controlled drugs.
- The list of controlled drugs that can be prescribed, supplied and / or administered by nurse independent prescribers is due to be extended.
- The Home Office is currently reviewing the form that the controlled drug register should take. The proposals are that the current form will be replaced with a requirement to maintain designated fields of information under specified headings.
- Accountable Officers will be able to authorise a person or class of persons to witness the destruction of controlled drugs.
- Operating department practitioners are to be allowed to possess and supply controlled drugs in an hospital operating department or theatre.
- The supply of a controlled drug for the purpose of administration in a ward or theatre will be permitted in accordance with the directions of a nurse independent prescriber (to the extent of the controlled drugs that they are authorised to prescribe), or a supplementary prescriber acting under a clinical management plan.
- A further pilot for Patient Drug Record Cards (PDRCs) is being carried out – an evaluation from this pilot will inform whether such a system should be rolled out nationally. If successful, PDRCs could become a legal requirement for all Schedule 2 injectable controlled drugs. A PDRC will provide a record of how much of a controlled drug is prescribed, dispensed, what is received in the patient's home, how much is administered, what is left and returned for safe destruction.
- Controlled drugs will be able to be written and transmitted electronically, signed with an advanced electronic signature.
- Software for electronic transmission of prescriptions (now called the Electronic Prescription Service) will capture both the time of issue of a prescription and the time at which the dispensed controlled drugs are handed to the patient.
- Information about prescribers who have restrictions placed on their prescribing of controlled drugs will be made accessible to all pharmacies over time.
- The prescriber's identification number, for both private and NHS prescriptions, will be recorded electronically in the controlled drug register.
- The name and professional ID of the pharmacist / dispensing doctor dispensing a Schedule 2 controlled drug will be recorded electronically in the controlled drug register.
- Any prescriptions for Schedule 2 and 3 controlled drugs will contain a patient identifier. In England this is the patient's NHS number, in Scotland the CHI number and in Wales it has yet to be decided, and will apply to both NHS and non-NHS prescriptions – this is currently good practice.
- Once electronic controlled drug registers are in common use they will become mandatory – when this happens keeping a running balance will also become a mandatory requirement. When electronic controlled drug registers become mandatory they will be expected to be kept for up to eleven years.

- All healthcare organisations including GP practices and community pharmacies will be required to send information on their controlled drug requisitions to the relevant NHS agency.
- Controlled drug prescriptions will be identifiable via a special marker.

## **Resources**

The Department of Health have a dedicated section of their website focusing on controlled drugs. This contains guidance on record keeping requirements, destruction and disposal of controlled drugs, private controlled drug prescriptions, monitoring and inspection arrangements, computerised prescriptions and registers, changes to the prescribing and dispensing of controlled drugs and further activity.

<http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/Prescriptions/ControlledDrugs/fs/en> .

Scottish Executive website:

<http://www.scotland.gov.uk/About/Departments/HD> .

Scottish Executive advice on the changes around prescribing and dispensing of controlled drugs, NHS HDL (2006) 27:

<http://www.show.scot.nhs.uk/publicationsindex.htm> .

Welsh Assembly Government website:

<http://new.wales.gov.uk/about/departments/dhss/?lang=en> .

NPC, "A guide to good practice in the management of controlled drugs in primary care (England)":

[http://www.npc.co.uk/controlled\\_drugs/CDGuide\\_2ndedition\\_February\\_2007.pdf](http://www.npc.co.uk/controlled_drugs/CDGuide_2ndedition_February_2007.pdf) .

The NPC are providing online training around controlled drugs – the changes and implications.

The NPC, "Competency Framework: Monitoring and inspecting the management of controlled drugs":

[http://www.npc.co.uk/pdf/CDI\\_Competency\\_Framework.pdf](http://www.npc.co.uk/pdf/CDI_Competency_Framework.pdf) .

RPSGB, Advisory Service:

<http://www.rpsgb.org.uk/informationresources/advisoryservices/legalandethicaladvisoryservice/index.html> .

RPSGB, Fitness to Practise and Legal Affairs Directorate. Fact Sheet: One. Controlled Drugs and Community Pharmacy:

<http://www.rpsgb.org/pdfs/factsheet1.pdf> .

RPSGB, Medicines, Ethics and Practice: A guide for pharmacists:

<http://www.rpsgb.org.uk/informationresources/downloadsocietypublications/#m> .

RPSGB, and Department of Health good practice guidance on the safer management of controlled drugs in secondary care:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_074513](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074513) .

Home Office website:  
<http://www.homeoffice.gov.uk/> .

The Advisory Council on the Misuse of Drugs:  
<http://www.drugs.gov.uk/drugs-laws/acmd/> .

British National Formulary:  
<http://www.bnf.org/bnf/> .