



Home Office

DLEU-Drug Legislation and Enforcement Unit
Floor 6, Peel Building, Marsham St London SW1P 4DF
Switchboard 0870 0001585 Direct Line 020 7035 0464
E-mail chris.edwards@homeoffice.gsi.gov.uk www.homeoffice.gov.uk

Secretaries of the Organisations
in the list appended to this letter

DH Gateway Ref No: 5093
Date 28 July 2005

Dear Sir/Madam

PUBLIC CONSULTATION-PROPOSED CHANGES TO MISUSE OF DRUGS LEGISLATION

1. I am writing to consult you on the Government's proposals to introduce a series of amendments to the Misuse of Drugs Regulations 2001, under the Misuse of Drugs Act 1971, in order to implement key elements of the action programme published in *Safer Management of Controlled Drugs* (December 2004) - the Government's response to the Fourth Report of the Shipman Inquiry. The Home Office is administering the consultation exercise which has been drawn up in consultation with the Department of Health. The final date for replies to this consultation to be accepted will be 21 October 2005. (E-mail: Regulationchange@homeoffice.gsi.gov.uk)

2. *Safer Management of Controlled Drugs* made clear the Government fully agreed that the current systems for managing controlled drugs needed strengthening to minimise the risks to patient safety of the inappropriate use of controlled drugs. However, as the Shipman Inquiry itself recognised, controlled drugs are used for a wide variety of clinical reasons and strengthened controls must be balanced with ensuring that patients can access the care they need and that the legitimate use of controlled drugs by healthcare professionals is not compromised.

3. The Government response developed through widespread consultation with key stakeholders set out a substantial programme of work to improve the management of controlled drugs in five key areas:

- monitoring and inspection;

- prescribing;
- the audit trail;
- providing information to patients about the safe handling and safe disposal of medicines;
- initial training and continuing professional development for healthcare professionals in relation to controlled drugs.

4. The proposed amendments to the Misuse of Drugs Regulations 2001 (the 2001 Regulations) set out in this letter are intended to implement some of the early changes to the prescribing of controlled drugs and strengthen the audit trail for controlled drugs across the NHS and private healthcare sector. These proposals have been prepared in consultation with, and on the advice of, the Advisory Council on the Misuse of Drugs (ACMD), the independent body established to advise the Government on drug misuse issues.

5. The Government has already consulted (on 21 May 2003) on its proposals to amend the 2001 Regulations to allow :

- all details on prescriptions for controlled drugs except the signature to be computer generated;
- computerisation of controlled drugs registers for drugs listed in Schedules 1 and 2 of the 2001 Regulations;
- computer generated requisitions or orders for Schedule 2 and 3 controlled drugs.

The changes agreed are expected to be implemented in July/August 2005. The Government has no immediate plans for electronic transmission of prescriptions for controlled drugs but will consider the appropriateness of allowing electronic CD prescriptions in the longer term.

6. A number of proposals in this and the earlier consultation also relate to legislation set out in the Medicines Act 1968 and Regulations made under that Act. The Medicines Act legislation is the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA will separately consult on those proposals in the normal way and advice will be sought from the Committee on Safety of Medicines.

Proposals : Prescribing of controlled drugs

Maximum validity of prescriptions

7. The Government propose to **amend Regulation 16 of the 2001 Regulations to place restrictions on the maximum validity of prescriptions for controlled drugs in Schedules 2, 3 and 4 to 28 days**. Currently, prescriptions for these controlled drugs may be dispensed up to 91 days from signing by the prescriber. The Government considers that such a period of time increases the chances

that controlled drugs might be dispensed beyond their clinical need and stored or diverted inappropriately. The purpose of the change is to minimise the scope for prescription forms to be used when a significant time has elapsed since the clinical need was originally identified.

8. As indicated in *Safer Management of Controlled Drugs*, the Government has considered the feasibility of developing good practice guidance to define exceptional circumstances when it might be appropriate to extend the 28 day validity. However, further consultation with key stakeholders has not identified any clinical need for this and the Government is therefore no longer proposing to introduce such an option.

9. *Safer Management of Controlled Drugs* also drew attention to the repeat dispensing arrangements recently established in the NHS. These arrangements enable patients to have medicines dispensed in several episodes rather than going back to their prescriber for a new prescription each time. Patients are given a single repeatable prescription, where the prescriber indicates that the medicines ordered maybe provided more than once and specifies the number of occasions they can be supplied. As part of the NHS arrangements, before the pharmacist provides the patient with the next supply, they need to satisfy themselves that the patient is still taking the medicines appropriately, there has been no change to their medication regime or their health. If the pharmacist thinks it would be inappropriate to make a further supply, they refer the patient back to the prescriber and notify the prescriber. The repeatable prescription can be valid for as many repeats as indicated and within the NHS arrangements valid for up to a year. When the repeats run out or after a year the patient has to return to the prescriber to get a new prescription.

10. **Views are sought on whether it would be appropriate to allow repeatable prescriptions for controlled drugs under similar arrangements to those for NHS repeat dispensing arrangements.** Appropriate legislation could be drafted to introduce different limits for repeatable prescriptions for controlled drugs such as only allowing a limited number of repeats, the repeatable prescriptions only being valid for six months or only allowing certain controlled drugs to be prescribed in this way.

Non-Medical Prescribing, Supply and Administration

11. The Department of Health and Home Office have already taken action to extend prescribing responsibilities to nurses, pharmacists and three Allied Health Professionals to:

- make it easier for patients to obtain the medicines they need;
- make better use of the skills of these professions;

- play an important role in the introduction of more flexible team working across the National Health Service (NHS) without compromising patient safety.

12. Nurse and pharmacist supplementary prescribers are now able to prescribe controlled drugs as part of a patient's individual Clinical Management Plan agreed with a doctor. The Government also proposes to :

- **add some Allied Health Professionals (AHPs) who as supplementary prescribers are able to prescribe controlled drugs in partnership with a doctor, under an agreed patient-specific clinical management plan with the patient's agreement.** The current AHPs for whom this is being considered are chiropodists/podiatrists, physiotherapists, radiographers (diagnostic and therapeutic) and optometrists:
- **expand the number of health professions who may supply or administer controlled drugs under Patient Group Directions, by adding occupational therapists, and prosthetists and orthotists.**

We would welcome views on these proposals.

Proposals : the audit trail for controlled drugs

13. The Inquiry findings highlight that, under current legal controls, there is no complete audit trail of the movement of controlled drugs from dispenser to patient to destruction of any unwanted drugs at the end of a course of treatment. Changes in the overall context in recent years - particularly the increasing emphasis on clinical audit - make it much less likely that a clinician could continue to practise without questions being asked. However, there are still a number of obvious gaps in the current arrangements that *Safer Management of Controlled Drugs* sought to address, in particular the need:

- to extend current arrangements for analysing the prescribing of controlled drugs to cover private prescribers;
- to make it possible, where necessary, to link information relating to all the prescribing by a single prescriber (whether in NHS or private practice) or to all the prescriptions for a single patient (whether from NHS or private sources);
- supply information in standardised formats on the flow of controlled drugs down the supply chain; and
- to collate and analyse this information centrally so that any apparent discrepancies/diversions can be further investigated at local level.

14. This consultation puts forward early proposals for closing some of the gaps. In the longer term, as *Safer Management of Controlled*

Drugs made clear, the Government will commission a more detailed scoping and feasibility study of a comprehensive IT approach to the audit trail for controlled drugs. We will then consult further with stakeholders before final decisions are taken.

Controlled drug prescriptions

15. The Government therefore proposes to **introduce a series of amendments to Regulation 15 of the 2001 Regulations to facilitate the monitoring and analysis of controlled drug prescribing, capturing both NHS and non-NHS activity** by requiring:

- any prescription for controlled drugs including private prescriptions to carry an identification number unique to each prescriber;
- similarly any prescription for controlled drugs including private prescriptions to carry a unique patient identifier (the NHS number), which will be used only as far as is necessary to identify any “double scripting” (patients obtaining supplies of controlled drugs from more than one prescriber). The Government is committed to analysis of anonymised data wherever possible and will consider development of a Code of Practice/further guidance on access to and use of confidential personal information in relation to this proposal, and on the obligations on prescribers and dispensers faced with patients who are unable or unwilling to supply their NHS number;
- non-NHS prescribers to use prescription forms to a standard format specified in the Regulations;
- completed forms to be submitted for analysis to the appropriate NHS reimbursement agency, currently the Prescription Pricing Authority (PPA) or equivalent in the devolved administrations for reconciliation after the controlled drugs have been dispensed. Generally, the forms will be sent to the PPA by the dispensing pharmacist.

16. The Government also proposes to **introduce a regulation to mandate the use of standard forms for any requisitions of controlled drugs and the submission of these forms to the PPA (or its successor body)**. In order to facilitate more comprehensive arrangements to monitor the use of controlled drugs outside the usual prescription route, the Government response in *Safer Management of Controlled Drugs* proposed to introduce a statutory requirement that any requisition or order for controlled drug stocks from a community pharmacy, wholesaler, manufacturer or other supplier be made in a standard format specified in regulations. There will be a further requirement on suppliers to submit the forms (or copies of the forms) to the PPA or successor body for analysis.

17. In the first instance, the Government proposes to focus this requirement on requisitions of controlled drugs by GP practices, out of hours services and other settings where controlled drugs are

administered to patients. At a later stage, subject to consultation and Ministerial approval at the time, the requirement will be extended to capture all requisitions of controlled drugs.

We would welcome views on the proposals outlined in paragraphs 15 - 17.

Safeguarding stocks of controlled drugs

18. All healthcare providers will be required to make an annual declaration as to whether they hold stocks of controlled drugs on the premises. Those that do hold stocks of controlled drugs will be required by the relevant NHS legislation to draft an appropriate Standard Operating Procedure (SOP) and to have it agreed - for primary medical service providers by the relevant PCT Accountable Officer, in the acute sector by the relevant NHS Trust's Accountable Officer, for private healthcare providers by the Healthcare Commission and for care homes and registered nursing homes by the Council for Social Care Inspection (or their equivalents in the devolved administrations) as part of the registration process.

19. The Government propose to **introduce a requirement that all healthcare providers holding stocks of controlled drugs should have and comply with the terms of an agreed Standard Operating Procedure (SOP)** which will be monitored as part of the new inspection arrangements. The content of SOPs will be informed by current best practice. The Department of Health will work with professional organisations and other key stakeholders to develop guidance clarifying a minimum set of criteria for SOPs that will allow sufficient flexibility for local circumstances.

20. The Government also proposes to **make a series of amendments to Regulations 19 and 20 of the 2001 Regulations for record keeping and controlled drugs registers to:**

- make clear that controlled drugs registers may include a running balance of stock. The Department of Health and the Home Office have agreed that the current regulations merely specify the minimum requirements of the controlled drugs register and do not prevent a pharmacy or GP practice including additional information.
- As an interim measure pending regulatory change, the Home Office wrote to RPSGB earlier this year to confirm that although the current regulations are silent on this issue, maintenance of a running balance in the controlled drugs register is a matter of good practice. RPSGB issued professional best practice guidance clarifying the position for its members in May 2005;

- allow the name and professional registration number of the prescriber and the name and registration number of the dispenser to be included in the controlled drug register.

21. Once computer generated Controlled Drugs Registers are in common use, subject to Minister's approval at the time, the Government intends to make the inclusion of a running balance a mandatory requirement.

The Government would welcome views on its proposals to strengthen the current arrangements for safeguarding stocks of controlled drugs (paragraphs 18 – 20).

Dispensing controlled drugs

22. The Government proposes to **introduce a requirement for dispensers to ask for the name, address and some form of personal identification of the person, whether patient or patient's representative, collecting the controlled drugs (unless already known)**. This requirement would apply to Schedule 2 controlled drugs only.

23. One of the main loopholes Shipman exploited was through collecting controlled drugs on behalf of the patient for whom he had prescribed them and then diverting the drugs to his own use. The Inquiry recommended as an additional check that pharmacists seek to establish the identity of anyone claiming to be collecting controlled drugs on behalf of patients – the Government agreed.

24. Every effort should be made to ensure patients have access to the medicines they need provided this does not put their safety at risk and pharmacists will have discretion to supply to patients or their representatives where no ID is presented. The amendment will make clear that a dispenser who uses his/her discretion to make a supply in the absence of identification is not committing an offence. The Department of Health will work with pharmaceutical organisations to issue guidance on what forms of ID will be acceptable.

25. The Government proposes to **introduce a parallel requirement for identification of healthcare professionals acting in their professional capacity on behalf of patients and patient's representatives, presenting a prescription or requisition for a controlled drug**. Where the healthcare professional is a prescriber, the identification offered should include their unique prescriber identification number (see paragraph 15).

26. The Government proposes to **amend Regulation 15 of the 2001 Regulations to allow the pharmacist or dispenser to alter a prescription in cases where there is a technical error but where the prescribing intention of the prescriber is clear**.

The Department of Health and the Royal Pharmaceutical Society of Great Britain (RPSGB) are working to define the types of errors that

would count as “technical errors” (eg impossible dates, disagreement between the amount ordered and dose quoted on the prescription) and the action which the dispenser could properly take in each case. This will be clarified in future guidance – a draft version summarising possible case scenarios is attached at Annex C. MHRA will separately consult on any changes required to medicines legislation to ensure consistency with these proposals for amendments to the 2001 Regulations. Depending on the MHRA consultation, the timing of this particular proposal may need to be rescheduled.

We would welcome your views on these proposals, in particular on the detailed proposals at Annex C for circumstances in which pharmacists would have discretion to amend prescriptions for controlled drugs where there are technical errors but where the prescribing intention of the prescriber is clear.

Controlled drugs in the community

27. The Government proposes to **make amendments to Regulation 27 of the 2001 Regulations on the destruction of controlled drugs in order to:**

- broaden the potential groups of people entitled to witness destruction of surplus stock controlled drugs;
- impose a new requirement to witness destruction of returns of controlled drugs from patients. This requirement will not be introduced until we have evaluated the pilot of the concept of a Patient Drug Record Card as described in *Safer Management of Controlled Drugs* (Chapter 4) and we will be consulting again at that point. In the meantime, the Government would welcome views on the categories of people who might appropriately witness such destructions.

28. In taking each of these proposals forward, there is a need to balance the requirement for a witness to be professionally independent of the person carrying out the destruction and for both to be professionally accountable for their actions. There is also a need to minimise interference with delivery of patient care at pharmacies and dispensaries.

29. The Government proposes to **make amendments to the Misuse of Drugs (Safe Custody) Regulations 1973 to remove:**

- the requirement for exemption certificates authorising the use of alternative cabinets to be issued on an annual basis;
- and any reference to “key” in the wording to take account of the development of new types of locking mechanisms.

We would welcome views on the proposals outlined in paragraphs

27 - 29.

Other future proposed amendment to misuse of drugs legislation

30. Although no formal discussion by ACMD has taken place, there is a proposal that in the future the schedules of the 2001 Regulations could be simplified to make the risk potential of each drug and subsequent regulation easier to understand. Information on the current schedules is at Annex A.

Although this does not form part of this consultation paper, addressees are welcome to make an initial comment on this proposal.

Impact of legislation on business

31. In publishing its response to the Inquiry's findings, the Government accepted that some of the proposed actions would impact on healthcare providers and made clear its view that any additional burdens were fully justified in the light of weaknesses in the current control systems revealed by the Inquiry. The initial start up costs required to invest in some of the additional safeguards proposed eg new IT software will be offset over time by savings in staff time released by for eg. relaxing the requirement for handwritten prescriptions and Controlled Drugs Registers and the new discretion for pharmacists to amend technical errors. The Government has also sought to minimise additional burdens on front line staff wherever possible by integrating improvements in the management of controlled drugs with wider initiatives to safeguard patients and provide high quality healthcare.

32. A Regulatory Impact Assessment giving an overview of the expected impact of all the actions and proposals set out in the Government's response to the Fourth Report of the Shipman Inquiry was published alongside *Safer Management of Controlled Drugs* in December 2004 - a copy is attached at annex B. In developing this consultation, the Home Office has looked at potential additional costs which might occur over and above those identified by the Department of Health in the attached RIA and considers that these will be minimal. The Government has endeavoured to include all relevant interests in developing these proposals and assessing their expected impact and would welcome any further views.

Application to England, Wales, Scotland and Northern Ireland

33. The proposed changes to the Misuse of Drugs Regulations 2001 would apply to in England, Wales and Scotland. The Department of Health and Social Services will be considering similar changes to the corresponding Regulations for Northern Ireland.

Northern Ireland has its own Misuse of Drugs Regulations which are

identical in form to those operating in England, Wales and Scotland. Northern Ireland correspondents are therefore asked to forward their comments to the Home Office address indicated. It should be noted, however, that there are references within this document to some structures which are not currently in place in Northern Ireland and so the NI Regulations will be worded accordingly.

Next Steps

34. **We would welcome views on:**

- **the possible use of repeatable prescriptions for controlled drugs (paragraphs 9 and 10);**
- **the possible simplification of the schedules (paragraph 30);**
- **any of the other proposed measures set out in this letter and on the related Regulatory Impact Assessment .**

35. Subject to consideration of any comments received and the views of Ministers, the planned date for regulation change is December 2005 although practical implementation of some of the changes will not take effect until the necessary systems and processes have been developed by the new NHS Business Services Authority. In addition, as highlighted at paragraph 6, some of these proposed changes to the Misuse of Drugs Regulations 2001 may require amendments to legislation set out in the Medicines Act 1968 and its Regulations.

Comments, using the attached response form at Annex D should be addressed to Chris Edwards, Drugs Legislation and Enforcement Unit, Home Office, Floor 6, Peel Building, 2 Marsham St, London SW1P 4GF by 21 October 2005.
(E-Mail:Regulationchange@homeoffice.gsi.gov.uk)

A summary of the responses received will be published within three months of the closing date of this consultation and will be made available on the Home Office web site.

36. A copy of this letter and attachments is also available online on the Home Office website (www.homeoffice.gov.uk). Copies of this letter in Braille, large font or audio will be made available on request. If you have any queries about this letter, please contact Chris Edwards on 0207 035 0464.

Yours faithfully

Jeremy Sare
Head of Drug Legislation Section.

This consultation follows the Code of Practice on Consultation the criteria for which are set below.

The six consultation criteria

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The full code of practice is available at: <http://www.cabinet-office.gov.uk/regulation/Consultation/introduction.htm>

Consultation Coordinator

If you have any complaints or comments about the consultation process, you should contact the Home Office consultation coordinator Pio Smith

by email at:

pio.smith31@homeoffice.gsi.gov.uk

Alternatively, you may wish to write to:

Pio Smith

Consultation Coordinator

Performance and Delivery Unit

Home Office

3rd Floor Seacole

2 Marsham Street

London

SW1P 4DF

Responses: Confidentiality and Disclaimer

The information you send to us may be passed to colleagues within the Home Office and/or published in a summary of responses received in response to this consultation. We will assume that you are content for us to do this, and that if you are replying by e-mail, your consent overrides any confidentiality disclaimer that is generated by your organisation's IT system. However, we will respect any wish for confidentiality that you make in the main text of your submission to us. Submissions from respondents may also be subject to release under the Freedom of Information Act 2000. If you have instructed us accordingly, the Home Office will ensure that your views are not attributed should they be released in this way.

ANNEX A

REQUIREMENTS WHICH ATTACH TO THE SCHEDULES OF THE MISUSE OF DRUGS REGULATIONS 2001

Schedule 1 - covers drugs such as ecstasy, LSD and cannabis that have no currently recognised medicinal uses. For this reason, they may not be prescribed by doctors and may only be possessed under Home Office licence for research and other special purposes. Persons such as police constables and customs officers are authorised by the 2001 Regulations to possess Schedule 1 drugs. Other persons require production, supply or possession licences which, as indicated above, are only granted for research or other special purposes. Licences are also required for import and export. In addition, Regulations 14 (documentation), 18 (marking of containers), 19, 20 (register-keeping requirements), 23 (preservation of records), 26 (furnishing of information) and 27 (destruction) apply. Schedule 1 drugs are subject to the statutory safe custody requirements; and researchers licensed to possess Schedule 1 drugs are required to keep them in a complying controlled drug (CD) cabinet.

Schedule 2 - includes cocaine, diamorphine (medicinal heroin), morphine, methadone. Schedule 2 drugs are also subject to the additional prescription requirements of Regulation 15; amongst other things, prescriptions must be handwritten by doctors. Regulations 14 (documentation), 16 (supply on prescription), 18 (marking of containers), 19, 20, 21, 23 (keeping and preservation of registers), 26 (furnishing of information) and 27 (destruction) also apply to Schedule 2 drugs. Most Schedule 2 drugs are also subject to the statutory safe custody requirements.

Schedule 3 - includes certain barbiturates, buprenorphine, temazepam and flunitrazepam. Certain health professionals e.g. doctors and pharmacists are authorised by the Regulations to produce, supply or possess Schedule 3 drugs. In other cases an appropriate written authority will be required. Licences are also required for import and export. The prescription writing (including handwriting) requirements apply to Schedule 3 drugs. In addition, Regulations 14 (documentation), 16 (supply on prescription) and, 18 (marking of containers) apply. No register need be kept but Schedule 3 drugs are subject to the requirements of Regulations 22, 23, 24 (keeping and preservation of records). Regulations 26 (furnishing of information) and 27 (destruction - producers and holders of written authorities to supply only) also apply to Schedule 3 drugs. In addition, some Schedule 3 drugs are subject to the statutory safe custody requirements.

Schedule 4 Part I - includes 33 benzodiazepines (eg diazepam, lorazepam and nitrazepam) and pemoline. Persons already authorised by the Regulations (eg doctors and pharmacists) or by a written Home Office authority to produce, supply or possess Schedule 4 Part I drugs will automatically be so authorised in respect of GHB and zolpidem. In other cases an appropriate written Home Office authority will be required. Licences are also required for imports and exports of Schedule 4 Part I drugs. The Regulation 15 prescription writing

(including handwriting) requirements do not apply to Schedule 4 Part I drugs. Regulations 22, 23 (keeping and preservation of records), 26 (furnishing of information) and 27 (destruction - holders of written authorities to produce only) also apply to Schedule 4 Part I drugs. Schedule 4 Part I drugs are not subject to the safe custody requirements.

Schedule 4 Part II - includes 54 anabolic substances e.g. nandrolone and testosterone. Persons already authorised by the 2001 Regulations (e.g. doctors and pharmacists) or by a written Home Office authority to produce, supply or possess* Schedule 4 Part II drugs will automatically be authorised in respect of these anabolic steroids. In other cases an appropriate written Home Office authority will be required. [* NB Possession licences are not required if the substances are in medicinal product form.]

Import and export licences are required for the trade in Schedule 4 Part II substances. The Regulation 15 prescription writing (including handwriting) requirements do not apply to Schedule 4 Part II drugs. Regulations 22, 23 (keeping and preservation of records), 26 (furnishing of information) and 27 (destruction - holders of written authorities to produce only) also apply to Schedule 4 Part II drugs. Schedule 4 Part II drugs are not subject to the statutory safe custody requirements.

Schedule 5 - covers weak preparations of certain controlled drugs e.g. codeine, kaolin and morph which are not liable to cause significant harm if misused. It is the lightest level of control. Certain health professionals e.g. doctors and pharmacists are authorised by the Regulations to produce, supply or possess Schedule 5 drugs. In other cases a written authority to produce or supply is required. Schedule 5 drugs are exempted from import, export and possession controls. They do not necessarily require a prescription; the prescription handwriting requirements do not apply to Schedule 5 drugs. Finally, they are subject to some record-keeping requirements.

REGULATORY IMPACT ASSESSMENT

for Safer Management of Controlled Drugs (published December 2004)

The Government's response to the Fourth Report of the Shipman Inquiry

The Government's response to the Fourth Report of the Shipman Inquiry, Safer Management of Controlled Drugs, is published today. This Regulatory Impact Assessment (RIA) gives an overview of the expected impact of the actions and proposals in the government response on public sector frontline staff, private and voluntary healthcare and social care organisations. The attached annexes a to e give further details on the measures likely to have the greatest impact.

2. The Government response sets out a substantial programme of work which will take several years to implement. It has been developed through a process of widespread consultation with relevant stakeholders, as described in more detail below. In the light of the serious concerns raised by the Shipman case and by the Inquiry's report, the government considers that there is a need to make an early start to implementation. In some cases, therefore, the government intends to proceed directly to implementation without further consultation. For actions in later stages of the work programme there will be further consultation as appropriate.

3. Some aspects of this document should therefore be regarded as a "final" RIA, while others are still of the nature of an initial or partial RIA. The Department of Health will publish further RIAs in due course as part of the consultations on particular proposals.

Purpose and intended effect

Objective

4. The objective of the Government's action programme is to safeguard patients, improve the quality of the use of controlled drugs (CDs) in the NHS and in the UK healthcare system generally, and to minimise the risk of diversion of CDs to illegitimate uses. In doing so, the Government wishes to avoid placing any barriers in the way of the appropriate use of CDs in modern healthcare.

Background

5. Harold Shipman diverted large quantities of CDs for his own criminal purposes. The Shipman Inquiry's Fourth Report gives a detailed analysis of the shortcomings in the systems then current in the NHS which enabled him to get away with these practices without detection for such a long period. The Inquiry concluded that significant changes were needed in order to provide patients with

proper safeguards, to deter future criminal activity, and to maximise the likelihood that any future activity of this kind would be speedily detected and stopped.

6. The government accepts the underlying objective of all the Inquiry's recommendations, and in most cases the solution proposed by the Inquiry. In a number of cases the government has concluded that there are better ways of achieving the desired objectives. In particular, the government has taken account of the major changes in the NHS since Shipman was active, above all the development of the concept of "clinical governance" and the underlying processes which are intended to help all NHS healthcare professionals to evaluate and improve the quality of the care they give to their patients. The action programme is therefore intended to work with the grain of these processes, partly because this will minimise any additional burden on frontline staff but mainly because improvements in the management of CDs should not be seen as an additional task but as an integral part of providing high quality healthcare.

7. In addition to responding to the Inquiry's recommendations, the government has taken account of parallel work from the National Prescribing Centre and from a special subcommittee of the Advisory Council on the Misuse of Drugs (ACMD). Some of their recommendations will be considered during the implementation phase and will be subject to further consultation. However, one major theme in the ACMD's work is the need to improve both initial training and continuing professional development for healthcare professionals in the safe and effective use of CDs. The government fully endorses this advice and its action programme includes a section on implications for training and development.

Risk assessment

8. Fortunately, criminal behaviour on the scale shown by Harold Shipman is extremely rare – though there have been a number of other recent cases of deliberate harm by healthcare professionals to their patients. Diversion of CDs to feed personal abuse or for financial gain is however more common. Experience of professionals working in this field suggests that most Primary Care Trusts (PCTs) may at any one time be dealing with up to 5 poorly performing doctors of whom one third may have a problem of substance abuse.

9. The existing system of controls over the use of CDs in healthcare has grown up over many years, and has not adapted to changes in the NHS and in the wider context. This has created the loopholes which Shipman so skilfully exploited. There are particular gaps in our information on private prescribing, on the use of CDs within GP practices, and in the "audit trail" for CDs administered in patient homes.

10. We therefore endorse the view of the Shipman Inquiry that "do nothing" is not a serious option, and that action is needed to reduce the risk of harm to patients and the risk of illegal diversion of CDs.

Options

11. The Inquiry's report contains 33 detailed recommendations. We have examined each recommendation and tested it, at the minimum, against the "do nothing" option. In a number of cases we have considered alternative ways of

achieving a similar objective. In the particular case of measures depending on improvements to IT systems, we have considered separately the options available from relatively modest enhancement to existing NHS IT systems and the options which will become available through full implementation of the National Programme for IT (NPfIT). Details are given in the Annexes of our assessment of the five sets of measures most likely to impact on frontline NHS staff or on the private or voluntary sectors.

12. For all other measures included in the action programme, our assessment is that there will be no significant impacts.

Benefits

13. A small number of recommendations have economic benefits, mainly through reducing time costs for frontline NHS staff (eg allowing electronic generation of prescriptions and dropping the requirement for CD prescriptions to be handwritten, which results in double entry as the information still needs to be entered into the computer-held patient notes).

14. However, the main benefits expected to flow from this action programme are improvements in the quality of patient care, better safeguards against harm to patients, and reduced opportunities of risk of diversion. We have not been able to quantify these benefits but our judgement, supported by the stakeholders we have consulted, is that they are more than adequate to justify the proposed action programme.

Costs

15. Our initial assessment of the financial costs of the action programme is as follows:

	£m	
	Set-up costs	Running costs (pa)
Monitoring and inspection	1.0	3.0
Audit trail	4.0	2.4
Information to patients	0.2	0.2
Training and development		2.2
Total	5.2	7.8

Running costs will be shared between central bodies such as the Healthcare Commission, the Commission for Social Care Inspection (CSCI) and the Prescription Pricing Authority (PPA) (£3.4m in total), NHS management (£1.4m) and NHS frontline staff including NHS contractors such as GPs and community pharmacies (£2.8m). Some components of the set-up cost, in particular IT costs, have not been fully estimated at this stage but will be assessed as part of the further scoping work described in the Annexes.

Equity and fairness

16. The proposed actions will apply equally to all healthcare providers, NHS and private sector. In the particular case of community pharmacy our assessment is that the impact will be similar for independent pharmacies as for pharmacies

belonging to the larger pharmacy chains.

Consultation with small business: the impact on small firms

17. A number of organisations impacted by these proposals fall into the category of “small firms”: some niche wholesalers, independent pharmacies, private healthcare clinics, hospices and care homes. We have endeavoured to include all relevant interests in the consultation described below.

In particular, we have consulted:

- the British Association of Pharmaceutical Wholesalers
- the Pharmaceutical Services Negotiating Committee
- the National Pharmaceutical Association.

Consultations so far have confirmed our view that these proposals will not have a disproportionate impact on small businesses.

Competition assessment

18. See the individual Annexes. Overall, our assessment is that none of the proposed measures will impact on the competitiveness of the various markets concerned.

Enforcement and sanctions

19. Our overall approach is to adopt the least burdensome approach to enforcement compatible with the overall objectives. For all aspects of professional behaviour we consider that the best means of enforcement is likely to be through professional codes of conduct and professional regulatory bodies such as the GMC. For NHS organisations, the principal means of enforcement will be through the Healthcare Commission or (for NHS Foundation Trusts) through Monitor, the Regulator for NHS Foundation Trusts. For the private and voluntary sectors, the Healthcare Commission (for healthcare providers) and CSCI (for care homes) have powers to inspect and, in extreme cases, de-register providers failing to show adequate compliance.

20. For a number of measures, especially those spanning both the NHS and private sectors, we propose to regulate through secondary legislation derived from the Misuse of Drugs Act 1971. This not only underlines the importance the government places on adequate safeguards but is also a convenient and familiar way of ensuring equity between the NHS and the private sector.

Monitoring and review

21. The implementation plan envisages four phases:

- January to August 2005 (Phase 1)
- September 2005 to March 2006 (Phase 2)
- April 2006 to March 2007 (Phase 3)

- April 2007 onwards (Phase 4)

We propose to monitor implementation and the impact on NHS frontline staff, private and voluntary organisations at the end of each phase. For this purpose, we will be setting up an overarching implementation steering group with all relevant stakeholders represented.

Consultation

22. The main proposals in the government's action programme were developed through four working groups covering all relevant stakeholders (see Annex f). In addition, the government took account of helpful work from the ACMD's Shipman Committee and from the National Prescribing Centre, both of which had carried out widespread consultation in developing their proposals.

23. Within government the Department of Health has worked closely with the Home Office, especially in relation to the proposals for monitoring and inspection (Annex a). We have also kept in close touch with colleagues in the health directorates of the devolved administrations, and shared our developing proposals with the Department for Education and Skills, the Department for the Environment, Food and Rural Affairs, the Healthcare Commission, CSCI, Monitor, and the central departments.

24. As already noted, we intend to set up an overarching committee of relevant stakeholders to steer implementation and we will set up working parties, supported by formal public consultation as needed, on individual strands of work.

Summary

25. Our conclusion is that to do nothing, in the light of the findings of the Shipman Inquiry, would be unacceptable; we would be failing to safeguard patients and we would be doing nothing to improve the general standards of the management of CDs in the NHS and in the private healthcare sector. Although we agree with the underlying objective of the Inquiry's own recommendations we think that in a few cases they would be impracticable to implement, would involve disproportionate cost or burden on frontline staff, or would fail to reinforce more general approaches to quality improvement. We believe that the action programme set out in the government's response, subject to further work and consultation on some individual aspects, represents a robust and proportionate response to the challenges posed by the Shipman case.

Department of Health
December 2004

Declaration

26. I have read the regulatory impact statement and I am satisfied that the benefits justify the costs.

Date.....8. 12 2004.....

Lord Warner
Parliamentary Under Secretary of State
Department of Health

RIA : ANNEX a: MONITORING AND INSPECTION

Objective. To provide mechanisms for internal and external quality assurance of the use and management of controlled drugs (CDs) by healthcare professionals; to deter and detect any significant abuse of CDs.

Background. Significant resources are already devoted to monitoring and inspecting some aspects of the use of CDs in the NHS, but the Shipman Inquiry pointed to

- some serious gaps (use of CDs in GP practices, the private sector),
- uneven standards of training for inspectors,
- a lack of overall coordination, with no systematic arrangements for integrating the inspections currently carried out by the Royal Pharmaceutical Society of GB (RPSGB) and the police Chemist Inspection Officers (CIOs).

The Inquiry recommended setting up a new integrated inspectorate with members drawn from both health professional and investigative backgrounds.

Risk assessment. We agree with the Inquiry that the current arrangements are inefficient and do not provide an adequate level of safeguard for patients. Changes in the NHS since Shipman was practising mean that there is now less risk of such serious abuse escaping detection for so long; but we think that the risk is still significant and justifies tightening up current arrangements. In addition, better arrangements for quality assessment and quality improvement should lead to better use of CDs generally resulting in better care for all patients needing CDs.

Options. Apart from the “do nothing option”, we considered two main options:

A. A new external inspectorate as proposed by the Inquiry;

B. A system based on current processes in the NHS, with internal quality assessment delivered through clinical governance processes and external quality assessment from the Healthcare Commission, supplemented by new arrangements for collaboration and information sharing between NHS and “partner” organisations (police, health regulatory bodies, health inspectorates etc). The key innovations would be

- a new statutory duty on all healthcare organisations to nominate a specific individual (a senior executive) to take responsibility for the safe and effective use of CDs in the organisation
- a new statutory duty of collaboration on all healthcare and partner organisations.

Costs and benefits. Initial costings suggested that Option A might incur costs of about £20m pa, while the net costs for Option B are estimated at set up costs of £1m and running costs of £3m pa. However, the main reason for preferring Option B is that it works “with the grain” of current NHS processes for delivering clinical quality improvements more generally, and is more likely to result in overall improvements in the effective and safe use of CDs in patient care. We have not formally estimated the expected benefits from Option B.

Equity and fairness. We propose to apply the new duties to all healthcare organisations (Primary Care Trusts, NHS Trusts, NHS Foundation Trusts, private healthcare organisations subject to inspection and regulation by the Healthcare Commission). We therefore believe that the new arrangements are equitable as between private and public healthcare organisations providing comparable services.

Impact on small firms. Some smaller private healthcare establishments may fall within the “small firms” definition. For any such organisation already complying with the provisions of the Misuse of Drugs Act 1971 there should be no additional impact other than the responsibility to nominate a “Proper Officer”. The duty of collaboration is likely to fall mainly on public sector organisations; any private sector organisation aware of potential CD offences by members of its staff would already be expected to share its concerns with the proper authorities and to collaborate with any subsequent investigation.

Competition. We have applied the competition filter test and are satisfied that the new regulation

- would have no differential effect between firms,
- would not affect market structure,
- would not discriminate against new entrants
- would not impact on the range of services or location of private healthcare providers.

So although the private healthcare sector is concentrated and marked by rapid technological change, we conclude that detailed assessment is not required.

Enforcement. We considered the option of proceeding by NHS guidance rather than by creating new statutory responsibilities. We do not consider that this would sufficiently emphasise the importance the government places on tightening up the management of CDs in all healthcare organisations. Also, NHS guidance would not directly bind private sector organisations. Enforcement would be through existing mechanisms (the Healthcare Commission for most NHS organisations and for private healthcare organisations, PCT contracts for NHS Foundation Trusts) and sanctions could in extreme cases result in losing authority to continue operating.

RIA : ANNEX b: CAPTURE OF INFORMATION ON PRIVATE PRESCRIPTIONS OF CONTROLLED DRUGS

Objective. To fill a major gap in information about the prescribing of controlled drugs (CDs).

Background. The NHS has a very complete source of information on drugs dispensed in the community, including CDs. Information on hospital prescribing is available within individual hospitals, and there is work in hand to collate this information to provide a national overview. In contrast, there is no information available at all on private prescribing. Anecdotal evidence suggests that this could form a significant proportion of all prescribing of CDs, especially in the treatment of drug abuse. The Shipman Inquiry therefore recommended that information on private prescriptions should be collected on a similar basis to that for NHS primary care prescriptions.

Risk assessment. Under current arrangements, it would be possible for a patient to receive prescriptions from an NHS prescriber and simultaneously – for the same condition – from one or more private prescribers. Such “double scripting” would not be easily detected. This creates a clear risk of harm to patients or of illegal diversion of CDs.

Options. The simplest option for capturing information about private prescribing, in the short term, is to require private prescribers to use a standard prescription form similar to that used for NHS prescriptions; and to require pharmacists to send the prescription after dispensing to the Prescription and Pricing Authority (PPA). The PPA can then key or scan in the information and analyse along similar lines to the standard analyses for NHS prescriptions.

In the longer term, it may be possible to offer private prescribers access to the NHS Electronic Transmission of Prescription (ETP) system, which would allow automatic capture of information on CD prescribing. This is not however part of the current programme of the National Programme for IT (NPfIT) and is regarded as of low priority.

Costs and benefits. We cannot fully assess the costs because of the lack of any robust data on the current level of private prescribing. However, costs to private prescribers of using one kind of prescription pad rather than another are likely to be minimal; and pharmacy professional organisations advise that “bundling up” private prescriptions for sending to the PPA would be a minor addition to their workload. Additional costs at the PPA are provisionally estimated at £1.4m set-up and £1.4m pa running costs.

Equity and fairness. The requirement would apply equally to all private prescribers and all pharmacies dispensing private prescriptions.

Impact on small firms. Expected to be minimal – see above.

Competition. We have applied the competition filter test and consider that our preferred option will have no impact on competition.

Enforcement. Our proposals on the audit trail (see Annex c) will ensure that any significant dispensing of private prescriptions will be detected and reconciled against the data on private prescribing. If it is found that a prescriber in a private hospital or clinic has failed to use the correct prescription pad and/or has failed to register his/her organisation as required under the Care Standards Act 2000, we would look to the Healthcare Commission in the first instance to take appropriate enforcement action which could in extreme cases result in loss of registration. Criminal sanctions would be considered only if there was clear prima facie evidence that the private prescriber was directly involved in criminal diversion of CDs.

RIA : ANNEX c: AUDIT TRAIL – SUPPLY CHAIN

Objective. To reconcile the quantities of controlled drugs (CDs) transferred between different points in the supply chain and thus to detect any illegal diversion or any supply relating to unregistered private prescribing.

Background. All organisations forming part of the supply chain – wholesalers, community pharmacists, hospitals, GP practices – are required to maintain “Controlled Drug Registers” (CDRs) showing the quantities of CDs moving in and out. These CDRs have to be made available for inspection allowing for an internal check on consistency. However, there is no simple means at present for checking that the quantities received at one point in the chain reconcile to those sent out from the previous point in the chain, and the system would not detect fraudulent entries in the CDRs or organisations failing to declare that they were using CDs.

Risk assessment. We have no direct evidence of deliberate illegal diversion of CDs at this point in the supply chain, but there is a clear potential. In addition, we do not think we are likely to get a true picture of the extent of private prescribing and dispensing of CDs (see Annex b) other than by the kind of whole-chain reconciliation described above.

Options. We have identified two possible options:

Option A - Picking a random sample of deliveries from wholesalers and following them down the supply chain;

Option B – Once electronic CDRs are in common use, requiring all organisations (wholesalers, community pharmacists, GP practices using CDs for practice use) to send information from their CDRs for central collation and reconciliation by the Prescription and Pricing Authority (PPA). Any significant discrepancies would be reported to Primary Care Trusts (PCTs) for further local investigation.

Our preliminary assessment is that Option A would be highly labour-intensive and, unless the sample is large, may well miss significant numbers of noncompliant private prescribers. Option B would make effective use of the potential power of computers, but would require CDRs to be kept in a standard form (or at least would require all IT systems to be capable of producing standard reports for transmission to PPA). We will carry out a more detailed scoping and feasibility study of Option B, with further consultation of stakeholders, before final decisions are taken.

Costs and benefits. The likely costs will be assessed as part of the scoping and feasibility study. We understand that community pharmacists and GP practices are keen to move towards electronic CDRs (which could be driven from their existing stock control systems) and consider that the costs of producing standardised reports are likely to be low provided that the format is specified at an early stage. IT software suppliers, for both GP and pharmacy systems, are already required to produce software which is compliant with the requirements of the National Programme for IT.

Equity and fairness. The proposals should have similar impact on all equivalent

organisations.

Impact on small firms. Independent pharmacies and GPs have been involved in the development of our proposals through their representative organisations. No significant impact has been identified. Small pharmacies and GP practices obtain their IT software from IT suppliers, thus spreading the development costs over many heads, and should not be at a significant disadvantage compared to large pharmacy chains where the IT development is inhouse.

Competition. We have applied the competition filter test and do not consider that the proposal will have a significant impact on competition as between smaller and larger wholesalers or pharmacists.

Enforcement. Subject to further consultation, we would propose to include the new requirements in the regulations under the Misuse of Drugs Act which will then apply to all relevant organisations, NHS or private. Wholesalers are licensed by the Home Office Drugs Inspectorate who will be in a position to ensure compliance. Community pharmacies already regularly return bundles of prescriptions to the PPA as part of the system for remuneration, so any missing returns of CDR data will be readily detected. PCTs hold the NHS contracts for community pharmacies and can follow up any non-compliance.

RIA : ANNEX d: STOCK RECONCILIATION IN GP SURGERIES

Objective. To ensure that GP surgeries using controlled drugs (CDs) maintain a regular reconciliation of stock levels against quantities received and supplied.

Background. Some (not all) GP practices keep stocks of CDs on the practice premises for personal administration to patients, eg for emergency pain relief. Such practices are required to keep CDs in a locked container and to maintain a controlled drug register (CDR). As the Shipman Inquiry noted, there have been no regular inspections of safekeeping arrangements in GP surgeries for at least 15 years. The Inquiry recommended that all GP practices using CDs should comply with a Standard Operating Procedure (SOP) agreed with the Primary Care Trust (PCT) and that the SOP should, among other things, specify the minimum frequency of reconciliation of the physical stocks of CDs held against the running balance in the CDR.

Risk assessment. Experience in the hospital setting shows that, even with good stock control systems and regular stock checks, quantities of CDs can still go missing. There is therefore a real risk of diversion. We have no reason to think that the risks are any lower in general practice – if anything they are likely to be higher because of the historical lack of external scrutiny.

Options. Apart from “do nothing” we do not think there is any practicable alternative to the Inquiry’s recommendations. Calculating the running balance in the CDR will be straightforward once electronic CDRs are allowed and are in common use. We propose therefore to take the earliest possible opportunity to amend the Misuse of Drugs Regulations 2001 (MDR) to allow electronic CDRs and will then work with professional organisations to promote their use. We envisage laying regulations towards the end of 2005-06, subject to further consultation, to make the use of SOPs mandatory.

Costs and benefits. We estimate that agreeing and operating SOPs could impose time costs on GP practices equivalent to £0.5m set-up costs and £0.6m annual running costs. There may also be some small additional IT costs but our understanding is that GP organisations are keen to see electronic CDRs introduced because any initial set-up costs will be rapidly offset by savings in administrative time compared with maintaining CDRs manually. Expected benefits are better stock control resulting in less waste of outdated stock and a reduced risk of diversion.

Equity and fairness. The proposal will impact on all GP practices equally, in both the NHS and the private sector.

Impact on small firms. See above (all GP practices are “small firms”). GP organisations have been involved in drawing up the proposals and are supportive.

Competition. We have applied the competition filter test and consider that our proposals will have no impact on competition in this market.

Enforcement. In the NHS, enforcement will in the first instance lie with PCTs who have a variety of levers available to ensure compliance, including in extreme cases

removing GP practices from their lists. In the private sector, enforcement will lie with the Healthcare Commission who could, in extreme cases, threaten to withdraw registration from practices or clinics failing to comply.

RIA : ANNEX e: PATIENT DRUG RECORD CARD

Objective. To audit the administration of injectable schedule 2 controlled drugs (CDs) in patients' homes and thus to minimise the risk of illegal diversion.

Background. One of the main ways in which Shipman amassed his lethal stock of diamorphine was by removing unused ampoules after the death of a patient and by keeping them himself rather than destroying them. The Shipman Inquiry therefore recommended a system for auditing the use of CDs in patients' homes and their recovery when no longer needed, using a "Patient Drug Record Card" (PDRC). This would be essentially a simple stock control card in which new supplies from pharmacies would be entered on the "credit" side and each administration as a "debit"; the running balance should then reconcile to the quantity of the CD still present in the patient's home or to the amount left over at the end of the course of treatment. The card would also be used to record the quantity of any CDs removed from the patient's home and their destruction (with a second witness) by a healthcare professional treating the patient or at a community pharmacy. The PDRC would be separate from the drug administration card already maintained by community nursing staff as part of the nursing record.

Because the system is likely to be quite labour intensive, the Inquiry recommended its use only for the most potentially dangerous CDs, injectable "schedule 2" CDs such as diamorphine.

Risk assessment. This is undoubtedly the weakest link in the audit chain and the risk of diversion is clear from Shipman's own case. Despite the technical difficulties, we do not consider that "do nothing" is an acceptable option.

Options. We have considered two main options. In both cases we would encourage healthcare professionals wherever possible to recover unwanted CDs from patients' homes and return them to a pharmacy for recording in a special "returns" CDR and witnessed destruction:

Option A: requiring staff from Primary Care Trusts (PCTs) to take a random sample of prescriptions for schedule 2 CDs dispensed at community pharmacies and following through the audit trail, using community nursing and GP records and local pharmacy "returns" CDRs.

Option B: a variant of the Inquiry's PDRC proposal, in which completed PDRCs would be returned to the Prescription Pricing Authority (PPA) for central collation and analysis and any apparent discrepancies reported to PCTs for further investigation.

Costs and benefits. There are issues with both options. Option A is likely to be labour-intensive for PCT staff (unless the sampling fraction is very low, in which case the deterrent effect may also be small); we have not yet formally costed this option. Option B involves some duplication with nursing records as already noted above and there seems at present no obvious way of avoiding this; it is also possible that a large proportion of the apparent discrepancies thrown up will prove to result from poor

record-keeping rather than from actual diversion. Our preliminary estimate is that Option B could result in running costs of about £0.8m pa for healthcare professionals, but this does not include any additional workload on PCT staff in following up queries. We intend to pilot option B (or possibly both options) and to consult further before taking firm decisions.

Equity and fairness. The proposal would impact equally on all settings in which CDs are administered, including hospices and care homes. There could be a small differential impact on community pharmacies depending on the age structure and other demographic features of the communities they serve.

Impact on small firms. See above – most community pharmacies, privately-run hospices and care homes would be regarded as care homes.

Competition. We have applied the competition filter test and conclude that the proposal would have no impact on competition in the relevant markets.

Enforcement. Action would lie mainly with community nursing staff and with PCT officers, who are directly employed by NHS organisations. Enforcement on private or voluntary organisations (eg nursing staff in hospices or care staff in care homes) would rest with the Healthcare Commission or the Commission for Social Care Inspection, who have adequate powers to ensure compliance including in extreme cases removing their registration.

RIA : ANNEX f: ORGANISATIONS INVOLVED IN THE WORKING GROUPS

Regulatory organisations

Healthcare Commission
Commission for Social Care Inspection
General Medical Council
Royal Pharmaceutical Society of GB
Nursing and Midwifery Council

Professional organisations

Royal College of General Practitioners
Joint Consultants Committee
General Practices Committee of the British Medical Association
Dispensing Doctors Association
Pharmaceutical Services Negotiating Committee
National Pharmaceutical Association
Company Chemists Association
Guild of Healthcare Pharmacists
Primary and Community Care Pharmacy Network
Royal College of Nursing
Royal College of Midwives
Community Practitioners and Health Visitors Association
Community and District Nursing Association

NHS organisations

NHS Confederation
NHS Alliance
South East London Strategic Health Authority
Bradford South and West PCT
Patient and voluntary associations
National Conference of Cancer Self-Help Groups
National Council for Hospice and Specialist Palliative Care
Macmillan Cancer Relief
British Pain Society

Other

Advisory Council on the Misuse of Drugs and its Shipman Committee
British Association of Pharmaceutical Wholesalers
Keele University Health Controls Assurance Unit
National Prescribing Centre
Doctor Patient Partnership
Medicines Partnership

Contact Point

For further information, contact:-

Chris Edwards,
Drug Legislation and Enforcement Unit,
Home Office,
Floor 6,
Peel Building,
2, Marsham St
LONDON
SW1P 4DF

Tel: 0207 035 0464

Fax: 0870 3369126

Date: 28 July 2005

ANNEX C : CONTROLLED DRUG TECHNICAL ERRORS ON PRESCRIPTIONS

This annex sets out our detailed proposals for the circumstances in which pharmacists would have discretion to amend prescriptions for controlled drugs where there are technical errors and where in their judgement the intention of the prescriber is absolutely clear. Pharmacists would not have discretion in other circumstances.

The following is assumed

:

- the pharmacist has no doubts as to the authenticity and validity of the prescription
- the pharmacist will not follow the suggested action if there is any doubt as to the safety of the action
- the pharmacist will follow any relevant RPSGB guidance, and – as for any other aspect of pharmacy practice - renders himself liable to disciplinary action if he does not follow professional requirements
- the pharmacist will keep appropriate records of any amendments made and will inform the prescriber (and, where appropriate, the PCT Accountable Officer) at the earliest convenient opportunity.

Error	Action	Comment
No date on prescription	Pharmacist must wherever possible take steps to confirm date of prescription from surgery records. If the surgery cannot be contacted, and the pharmacist has no reason to doubt the authenticity of the prescription, they may dispense but should inform the PCT Accountable Officer of the circumstances.	RPSGB will consider issuing further guidance.
Impossible date (e.g. 31 April)	Infer correct date from quoted information. Where possible, take steps to confirm the correct date of the prescription from the patient, their representative or surgery records but discretion to dispense even where confirmation cannot be obtained.	
Obviously wrong date (e.g. year in advance)	As above – where possible take steps to confirm correct date, but discretion to dispense in absence of confirmation.	
No quantity stated, but dose and duration given	Dispense on the basis of the prescribed dose and duration.	

Error	Action	Comment
No quantity or duration stated, but dose is given	Where possible, contact prescriber to confirm quantity required and dispense the required amount. If prescriber is not contactable, dispense emergency supply based on the stated dose.	RPSGB will consider issuing further guidance.
Quantity in words only	Dispense in accordance with the prescriber's intentions, if there is no doubt over the intended quantity in relation to the dose and treatment period (see below).	RPSGB will consider issuing further guidance.
Quantity in figures only	Dispense in accordance with the prescriber's intentions, if there is no doubt over the intended quantity in relation to the dose and treatment period (see below).	RPSGB will consider issuing further guidance.
Conflict between specified quantity, dose and length of the prescription	Dispense on the basis of the dose prescribed and the length of the prescription, if there is no reasonable doubt that this was the prescriber's intention.	RPSGB will consider issuing further guidance.
No form stated	Dispense a clinically appropriate form provided the pharmacist has taken reasonable steps to ensure that the form is appropriate for the patient	RPSGB will consider issuing further guidance.
No dose quoted – new patient	Only dispense if prescriber can be contacted and dose confirmed – no discretion to amend prescription in absence of confirmation.	RPSGB will consider issuing further guidance.
No dose quoted – existing patient	[Our provisional view is that this should be treated exactly as for the previous example, ie the pharmacist should dispense only if the prescriber can be contacted – otherwise the pharmacist cannot be confident that the dose has not changed since the	

Error	Action	Comment
	previous prescription. We would however welcome views on this point.]	
Relatively simple spelling mistake eg in drug name	Dispense provided the pharmacist has no doubt about the intentions of the prescriber.	
Missing prescriber identifier or patient identifier	Dispense provided the pharmacist knows the prescriber/patient (or has taken steps to identify the prescriber/patient). Where possible pharmacist should add the identifier.	RPSGB will consider issuing further guidance.
Incorrect prescriber or patient details (eg minor error in name or clearly incorrect identifier)	Dispense provided the prescriber's intentions are clear and the pharmacist has no reason to doubt the authenticity of the prescription. Where possible the pharmacist should correct the errors, but is not expected to check the accuracy of the identifiers if they are not obviously incorrect.	RPSGB will consider issuing further guidance.
For prescriptions for substance misuse – where the doctor writes an impracticable day for collection of e.g. methadone e.g. Bank holiday Monday	Pharmacist has discretion to supply on the last day that the pharmacy is open before bank holiday Monday e.g. Saturday or Sunday	

ANNEX D

**Consultation Response - please e-mail to
Regulationchange@postShipman@homeoffice.gsi.gov.uk
Alternatively, send by hard copy by 21 October 2005 to:**

Chris Edwards,
Drug Legislation and Enforcement Unit,
Floor 6,
Peel Building,
Marsham St,
London
SW1P 4GF

From: _____

**CONSULTATION LETTER: PROPOSED CHANGES TO THE MISUSE OF DRUGS
LEGISLATION**

I have the following views on:

- **The possible use of repeatable prescriptions for controlled drugs under similar arrangements to those for NHS repeat dispensing arrangements** (paragraphs 9 and 10)

- **The possible simplification of the Schedules** (paragraph 30)

- **The other proposed measures set out in this letter and the attached RIA**

Paragraph 7- maximum validity of prescriptions

Paragraphs 11 &12- Non-medical prescribing, supply and administration

Paragraph 15- proposals to facilitate monitoring/analysis of controlled drug prescribing

Paragraph 16&17- mandate the use of standard forms for any requisition of controlled drugs and the submission of these forms to the PPA

Paragraphs 18 &19- healthcare providers to have standard operating procedures if they hold stocks of controlled drugs on their premises

Paragraph 20- record keeping and registers

Paragraph 22- dispensers to ask for personal identification from person presenting a prescription for controlled drugs

Paragraph 25- identification of healthcare professionals presenting a prescription or requisition for controlled drugs

Para 26 and Annex C- proposals to allow pharmacist or dispenser to alter prescriptions where there is a “technical error” but where the prescribing intention of the prescriber is clear

Para 27- witnessing destruction of CD's

Regulatory Impact Assessment – Annex B

** My reply may be made freely available.*

** My reply is confidential.*

** My reply is partially confidential (indicate clearly in the text any confidential elements)*

Signed: _____

** Delete as appropriate*

Addressees

1. Advisory Council on the Misuse of Drugs
2. Animal Health Distributors Association (UK) Ltd
3. Animal Medicines Training Authority
4. Association of Anaesthetists
5. Association of British Pharmaceutical Industry
6. Association of Chief Police Officers of England, Wales and Northern Ireland
7. Association of Chief Police Officers in Scotland
8. Association of Clinical Biochemists
9. Association of Clinical Pathologists
10. Association of Nurses in Substance Abuse
11. Association of Private Hospital Pharmacists
12. Association of Supervisors of Midwives
13. Association of Veterinary Surgeons in Northern Ireland
14. Association of Wholesalers to the Veterinary Profession
15. The Biochemical Society
16. BLWA Ltd (Association for the Laboratory Supply Industry)
17. Board of Community Health Councils in Wales
18. British Academy of Forensic Sciences
19. British Association for Chemical Specialities
20. British Association of Generic Distributors (BAGD)
21. British Association of Homeopathic Manufacturers
22. British Association of Pharmaceutical Wholesalers
23. British Association of Prosthetists and Orthotists
24. British Chemical Distributors and Traders Association
25. British Dental Association
26. British Dental Association (Belfast Office)
27. British Generic Manufacturers Association
28. British Herbal Medicines Association
29. British In Vitro Diagnostics Association
30. British Institute of Regulatory Affairs
31. British Medical Association
32. British Medical Association (Belfast Office)
33. British Medical Association (Scottish Office)
34. British Pain Society
35. British Pharmacological Society
36. British Veterinary Association
37. British Veterinary Association (Scottish Branch)
38. Chartered Society of Physiotherapists
39. Chemical Industries Association Ltd
40. Chemist and Druggist
41. Chief Area Nurse Officers in Scotland
42. Chief Pharmacists NHS Trusts
43. Chief Pharmacists/Senior Pharmaceutical Advisers PCT's
44. Clinical Governance leads of NHS Trusts and PCT's
45. College of Occupational Therapists
46. Commission for Social Care Inspection
47. Commissioner of Police of the Metropolis

48. Community and District Nursing Association
49. Community Practitioners and Health Visitors Association
50. Company Chemists' Association Ltd
51. Confederation of British Industry
52. Department for Education and Skills
53. Department of Health and Social Security, Isle of Man
54. DrugScope
55. Forensic Science Society
56. General Dental Council
57. General Medical Council
58. General Medical Services' Committee (via DH)
59. Guild of Healthcare Pharmacists
60. Health Professions Council
61. Healthcare Commission
62. Independent Healthcare Forum (represented on the Controlled Drugs Advisory Group)
63. Institute of Health Services Management
64. Joint Consultants' Committee (via DH)
65. Joint Royal Colleges Ambulance Liaison Committee
66. MacMillian Cancer Relief
67. Monitor, Independent Regulator for NHS Foundation Trusts
68. NHS Confederation
69. NHS Foundation Trusts
70. National Board for Nursing, Midwifery and Health Visiting for Northern Ireland
71. National Board for Nursing, Midwifery and Health Visiting for Scotland
72. National Conference of Cancer Self Help Groups
73. National Council for Palliative Care
74. National Institute for Biological Standards and Control
75. National Office of Animal Health
76. National Patient Safety Agency
77. National Pharmaceutical Association
78. North of Ireland Veterinary Association
79. Nursing and Midwifery Council
80. Pathological Society of Great Britain and Ireland
81. Patients Association
82. PCT chairs of professional executive committees
83. PCT Chief Executives
84. PCT Prescribing leads
85. Pharmaceutical Contractors' Committee (Northern Ireland)
86. Pharmaceutical General Council (Scotland)
87. Pharmaceutical Journal
88. Pharmaceutical Services Negotiating Committee
89. Pharmaceutical Society of Northern Ireland
90. PHLS Central Public Health Laboratory Service Board
91. Prescription Pricing Authority
92. Proprietary Association of Great Britain
93. Registered Nursing Homes' Association
94. Release
95. Royal College of Anaesthetists
96. Royal College of General Practitioners
97. Royal College of Midwives
98. Royal College of Midwives (Scottish Board)
99. Royal College of Nursing of the United Kingdom

100. Royal College of Nursing (Scottish Board)
101. Royal College of Obstetricians and Gynaecologists
102. Royal College of Paediatrics and Child Health
103. Royal College of Pathologists
104. Royal College of Veterinary Surgeons
105. Royal Pharmaceutical Society of Great Britain
106. Royal Pharmaceutical Society of Great Britain (Scottish Executive)
107. Royal Pharmaceutical Society of Great Britain (Welsh Executive)
108. Royal Society
109. Royal Society of Chemistry
110. Scottish Association of Health Councils
111. Scottish Association of Nurse Administrators
112. Scottish Executive
113. Scottish General Practitioners Committee
114. Scottish Health Association pharmacy leads
115. Scottish Health Board General Managers Group
116. Scottish Joint Consultants Committee
117. Society of Chiropractors and Podiatrists
118. Society of Radiographers
119. Strategic Health Authority pharmacy leads
120. Transform
121. Turning Point
122. United Kingdom Central Council for Nursing, Midwifery and Health Visiting
123. Veterinary Medicines Directorate
124. Welsh Assembly, Pharmaceutical Division
125. Welsh Medical Committee
126. Welsh Nursing and Midwifery Committee
127. Welsh Pharmaceutical Committee