

Monitoring and inspection of Controlled Drugs: role of the Society's inspectors

The Royal Pharmaceutical Society's chief inspector, **Jackie Giltrow**, explains the new role of the Society's inspectorate in the monitoring and inspection of Controlled Drugs in community pharmacies in England from January 2007 and in Scotland from March 2007, with observations on the situation in Wales

Few practising health care professionals will have been unaffected by the implementation of recommendations made in the fourth report of the Shipman Inquiry,¹ published on 15 July 2004. As a result of the changes to the Misuse of Drugs Regulations 2001 and Royal Pharmaceutical Society guidance on Controlled Drugs (CD) issues such as running balances,² the report and its recommendations have had a far reaching impact on many members of the profession, who are grappling with the practicalities of the new legislative and good practice requirements. Against this backdrop, plans for the monitoring and inspection of compliance with the legislation and relevant codes of practice have been drawn up ready for implementation early next year.

This article looks at the background to the monitoring and inspection proposals and the role of the Society's inspectorate in the new proposals. It is important to note that the Society's inspectors will be undertaking CD monitoring and inspection in community pharmacies in England and Scotland only.

Background

In the fourth report of the Shipman Inquiry, Dame Janet Smith, who chaired the inquiry, identified systemic shortcomings that permitted Harold Shipman to obtain the large quantities of CDs used to kill his victims. The report contained 33 recommendations to provide better patient protection.

The Society responded by setting up a Shipman Inquiry working group to formulate responses to the inquiry reports and look at future work. In November 2004, the working group formulated a response to the fourth report, the full contents of which can be found on the Society's website.³ The response highlighted the fact that the Society's inspectorate had the professional expertise required to inspect and monitor CDs and should be centrally involved in developing any multidisciplinary CD inspection. Close links between the inspectorate and any new CD inspection body would be an essential requirement. The Society stated that, with appropriate resources and powers, the inspectorate could extend its enforcement activity both within community pharmacies and to other establishments. The skills and knowledge of the inspectorate meant that it was ideally placed to have a central role in the formation of CD inspection, and it had the professional expertise to carry out the CD inspection function within community pharmacies.

"Safer management of Controlled Drugs: the Government's response to the Fourth

Report of the Shipman Inquiry (England only)"⁴ was published in December 2004. In this response the Government made it clear that it fully agreed with the inquiry that the current systems for managing CDs needed strengthening to minimise the risks to patient safety from the inappropriate use of CDs. The Government did not, however, accept that a separate CD inspectorate outside existing clinical governance arrangements would be the best way of achieving this. The Government favoured instead a system working within and alongside existing governance arrangements. It was thought that this approach would build on the expertise of organisations that currently monitor and inspect aspects of the management of CDs, and maximise the ability to detect poor practice in CD management by combining this with information on other aspects of clinical practice. The overall monitoring and inspection arrangements would be subject to assurance by the Healthcare Commission.

The Government stated that, subject to further consultation with the Society and to Parliamentary approval of any legislative changes required, the Society's inspectorate would be invited to include, as part of its routine inspections of community pharmacies, a check on the management of CDs, including examination of CD registers and storage of CDs. (Currently, the role is carried out by police CD inspectors.)

Standards for inspection

In November 2004, the Department of Health set up a Shipman inspection subgroup, chaired by the Society's chief inspector, Jackie Giltrow. The group included representatives of those organisations affected by the Government recommendations (eg, Healthcare Commission, Commission for Social Care Inspection, primary care trusts, Dispensing Doctors Association and CDs inspectors). The terms of reference of the group, in the context of monitoring and inspection of CD included:

- To advise for each type of visit on those aspects of the use of CDs that should be examined in the course of the visit, on the standards which could reasonably be expected of a competent health care or social care provider in each sector;
- To advise on the management of information by those carrying out developmental visits and inspections; and
- To advise on the competencies and training required for those who will carry out the developmental visits and inspections.

Panel 1: Core activities for CD monitoring and inspection

- Personnel and registration details
- Lines of accountability for management of CDs
- Standing operating procedures
- General adequacy of premises
- Security and safe custody
- Examination of stock/patients' own medicines held
- Register, records and audit
 - CDs obtained
 - CDs supplied
 - CDs administered
- Prescribing
- Destruction

As a result of the work undertaken by the Shipman inspection subgroup, agreement was reached on the standards for inspection across the whole of health and social care.⁵

The standards for inspection set out the core activities that should be included in an inspection and cover areas such as ensuring safe storage arrangements, accountability and proper record keeping (see Panel 1).

The suggested frequency of visits is a minimum 10 per cent random sample to be inspected each year and as a general principle notice should be given of routine inspections (although not a legal requirement). All inspections should comply with the 10 principles of inspection set out in the Government's Policy on Inspection of Public Services (see Panel 2).⁶

Role of the Society's inspectorate

Following agreement with the Government and the Scottish Executive, and to avoid duplication of inspection by other agencies, the Society's inspectors are to include inspection of CDs in their routine inspections of community pharmacies in England from January 2007 and in Scotland from March 2007. Routine visits to pharmacies currently take place on average at least once every three years. Police CD inspectors will no longer routinely visit community pharmacies in England and Scotland. Instead the police will have a wider remit across the whole of health and social care in relation to the management and use of CDs. The Society's inspectors will continue to work closely with the police across England, Scotland and Wales.

Details of implementation of the Shipman recommendations in relation to monitoring and inspection of CDs in community pharmacies in Wales have yet to be finalised, but the

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Panel 2: Inspection principles

Public services inspection should:

- Pursue the purpose of improvement
- Focus on outcomes
- Take a user perspective
- Be proportionate to risk
- Encourage self-assessment by managers
- Use impartial evidence, wherever possible
- Disclose the criteria used for judgement
- Be open about the processes involved
- Have regard to value for money, including that of the inspecting body
- Continually learn from experience

Panel 3: Responsible bodies

The responsible bodies for the purpose of co-operation between health bodies and other organisations include:

- Primary care trusts, health boards, NHS trusts, NHS foundation trusts, strategic health authorities, independent hospitals
- Healthcare Commission (England)
- Commission for Social Care Inspection (England)
- NHS Business Services Authority (England)
- Common Services Agency (Scotland)
- Some special health boards (Scotland)
- Police forces
- Local authorities
- Regulatory bodies

Society's inspectors will continue their normal routine inspections of pharmacies.

From 2007, the Society will require a periodic declaration from pharmacy owners in relation to the management and use of CDs within each of their pharmacy premises. This declaration will become part of the annual premises retention fee cycle, backed by new legislation, which applies to England and Scotland.⁶ The pharmacy inspection and inspection cycle will be informed by these declarations and other tools such as self-assessments, visits data and complaints.

During the course of routine monitoring and inspection, the inspectorate will check compliance with the legislation and any professional guidance issued by the Society. The aim of inspections will be to help pharmacy owners, pharmacists and other employees to achieve compliance through assistance, advice, guidance and support. Visits will be used to educate pharmacists and their staff to develop safe systems in the management and use of CDs and to take responsibility for service provision to ensure patient safety. Promotion of improvements and compliance is a valuable part of any inspection process. A report form will be completed as a consequence of the visit and a copy of the form will be made available to the pharmacy owner or superintendent pharmacist. Any CD concerns reported as part of the visit will be disclosable (see below).

The monitoring and inspection process will be backed by a planned programme of implementation of professional guidance to pharmacists and registered technicians in relation to the management and use of CDs. In particular, the Society has highlighted areas — such as technical omissions, running balances, prescribing of CDs, use of identification when CDs are collected from pharmacies — that require further guidance to be provided to the profession. This guidance will be drafted with the input of a variety of stakeholders.

Accountable officers

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 apply to England and Scotland only and will place a requirement on “designate bodies” (eg, primary care trusts, NHS trusts, NHS foundation trusts, independent hospitals and health boards) to appoint an “accountable officer”.

The accountable officer will be responsible for a range of issues involving effective management and use of CDs within organisations subject to their oversight. Importantly, the proposed legislation will also place a statutory duty on “responsible bodies”, such as the Society, to co-operate with accountable officers and other responsible bodies and share information relating to CD concerns (see Panel 3).

Duty of co-operation

One problem identified during the Shipman Inquiry involved the failure of agencies to share information relating to concerns about Shipman. As a result, he remained undetected for many years. In an effort to prevent a similar failure in the future the Government intends to introduce legislation to allow information sharing between relevant bodies. Under the proposed legislation, responsible bodies will have a general duty to co-operate with each other in identifying cases involving the management and use of CDs and determining what action may need to be taken.

As well as having a general duty to co-operate, a responsible body may disclose to any other responsible body any information it possesses that it reasonably considers should be shared for the purpose of identifying cases in which action may be needed in relation to the management or use of CDs. There are some caveats on disclosure to ensure that individuals' rights under other legislation are protected.

In certain circumstances a responsible body must notify the relevant accountable officer either when an investigation into a matter of

concern in relation to CDs starts or when it is completed. As is currently the case, complaints received by the Society that involve CDs will be investigated by the Society inspector. Information will be shared with the relevant accountable officer, who in serious cases could decide to convene an incident panel, which would consist of officers from a variety of responsible bodies. The accountable officer could arrange for investigation into the concern and take any required action.

The Society welcomes the opportunity to participate in the new arrangements for monitoring and inspecting CDs. No doubt there are challenging times ahead to ensure that the burden of regulation does not stifle the proper use of CDs, but an important part of the new arrangements is to ensure that good practice is pursued through a framework of support, assistance, education and guidance.

With the Healthcare Commission having oversight of the new arrangements, there will be a feedback mechanism, which can act as a check and balance to identify whether or not the new monitoring and inspection arrangements work in practice. If the new regime raises the standard of practice in this area then it will have had the desired outcome.

It is too early to know how the new monitoring and inspection arrangements will work in practice and all who have been involved in the proposals acknowledge that criminality involving CDs can never be eliminated. It is hoped that, with better networks and intelligence sharing, serious issues involving health and social care professionals will be identified at an earlier stage and appropriate action taken.

Health care professionals affected by the changes to the legislation should recognise that the point of the exercise is not to prevent them legitimately managing and using CDs. Shipman's actions exposed weaknesses in the system of management and use of CDs that required strengthening. It is hoped that pharmacists will use the inspector's visit to request guidance and assistance on how to ensure compliance when handling and using CDs.

References

1. The Shipman Inquiry. Fourth report: The regulation of Controlled Drugs in the community (CM 6249). London: The Stationery Office; 2004.
2. Practice and Quality Improvement Directorate. Maintaining running balances of stock in Controlled Drug registers. *Pharmaceutical Journal* 2005;274:663.
3. Royal Pharmaceutical Society. Response to the recommendations of the Shipman Inquiry fourth report: The Regulation of Controlled Drugs in the community. London: The Society; 2004. Available at: www.rpsgb.org/pdfs/shipmaninqrep4resp.pdf
4. Department of Health. Safer management of Controlled Drugs, the Government's response to the fourth report of the Shipman Inquiry. London: The Department; 2004.
5. Department of Health. Monitoring and inspection guidelines: core activities for CD monitoring and inspection work — primary care. London: The Department; 2006.
6. Office of Public Services Reform. The Government's policy on inspection of public services. London: Cabinet Office; 2003.
7. Controlled Drugs (Supervision of Management and Use) Regulations 2006. SI 2006 No 3148. London: The Stationery Office; 2006.

More on Society inspections

Further information on Society inspections can be found on the “Inspectorate” page on the Society's website (www.rpsgb.org/protectingthepublic), which also gives details of how to contact your local inspector (who may change from January 2007 following a reorganisation of inspectors' areas) and support staff in the Fitness to Practise and Legal Affairs Directorate.