Health and Social Care Board

Medicines Safety Matters

Newsletter for Prescribers & Community Pharmacists

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Inside this issue:

Learning from Adverse Incidents involving Controlled Drugs

This newsletter focuses on learning from adverse incidents involving Controlled Drugs (CD) that have been reported to the HSCB over recent months.

Background

Compliance with all controlled drugs' legislation is essential to ensure the delivery of safe and efficient services. In addition to the Medicines Act 1968, CDs are governed by The Misuse of Drugs Act 1971 and The Health Act 2006 and their regulations. The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 laid out under the Health Act describe the responsibilities of Accountable Officers to secure the safe management and use of CDs for their organisation. One of these responsibilities is to ensure GP practices and community pharmacies have in place adequate and up-to-date Standard Operating Procedures (SOPs) in relation to the management and use of CDs. **SOPs legally must cover:**

- Who has access to CDs
- Where CDs are stored
- Security in relation to storage, and transportation, of CDs as required by misuse of drugs legislation
- Disposal and destruction of CDs
- Who is to be alerted if complications arise
- Record keeping including maintaining relevant CD registers (under misuse of drugs legislation) and records of Schedule 2 CDs returned by patients.

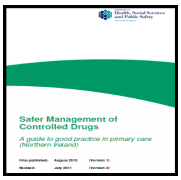
SOPs should also cover all aspects of risk management for:

- Ordering
- Storing
- Prescribing
- Dispensing
- Recording
- Supplying
- Administering and
- Destruction of CDs

- SOPs should be reviewed and updated regularly and reflect learning from adverse incidents.
- Relevant staff should be trained on, and sign up to, SOPs and adherence to SOPs should be monitored.

Detailed guidance on the management of CDs in primary care can be found in the:

- DHSSPS guide to Safer Management of Controlled Drugs July 2011[1] and
- HSCB Guidance for Developing a CD SOP for Prescribers.[2]



1. http://www.dhsspsni.gov.uk/safer-management-of-controlled-drugs-a-guide-to-good-practice-in-primary-care-version-2-july-2011.pdf
2. http://primarycare.hscni.net/PharmMM_Medicines_Governance.htm

Storage of CDs

Several incidents have been reported involving issues with storage arrangements for CDs. These include:

- Theft of CDs from community pharmacies and from vehicles
- Incorrect selection of CDs with similar names
- Stock loss due to lack of appropriate storage managements

Action for Prescribers and Pharmacists:

1. Schedule 2 and the following Schedule 3 CDs, temazepam, buprenorphine, flunitrazepam and diethylpropion **must be stored in a locked receptacle:**
   - For community pharmacies, storage of these medicines (including those dispensed and awaiting collection) should be in a time-delay safe
   - For GPs practices, storage could be in a doctor's bag or a secure cabinet on the premises
   - CDs should not be left in a vehicle overnight or in a vehicle left unattended for long periods.
2. Keep CD stock at reasonable levels. Use dividers/separate shelves where possible, to prevent the mix-up of products containing similar drugs or products with similar strengths and packaging. Store CDs in their original packaging.

Recording CDs

Several incidents have been reported involving discrepancies in the CD register balance.

Action for Prescribers and Pharmacists:

1. Running balances should be maintained for all Schedule 2 CDs and systems should be in place to ensure regular stock reconciliation.
2. It is the responsibility of the GP/pharmacist to ensure accurate entries are made in the CD register on the day of receipt/supply of a Schedule 2 CD, or if that is not reasonably practical, on the following day.
3. When a CD is dispensed, details should not be entered in the CD register until after the CD has been supplied to the patient or patient's representative or healthcare professional.
4. It is recommended that, where possible, two members of staff should sign entries in the CD register to confirm they are accurate.
5. SOPs should clearly define action to be taken if a discrepancy arises in relation to controlled drug balances.

Ensure Timely Supply of Controlled Drugs to Patients

Incidents have been reported involving the delayed supply of CDs to patients resulting in some cases, in a delay in commencing treatment. Delays were due mainly to:

- **Prescriptions not complying with CD regulations (see below)**
- **Inability to obtain the required CD during OOHs**
- **Faxing of prescriptions for Schedule 2 and 3 CDs to community pharmacies.**

Action for Prescribers:

1. Incorrectly written prescriptions for Schedule 2 and 3 CDs are not legally valid. Pharmacists cannot supply CDs without a legally valid prescription, therefore necessary amendments should be made in a timely manner. Computer records should be updated with prescription amendments to ensure an accurate medication history is maintained. It should be noted that a faxed copy of a prescription does not fall within the definition of a legally valid prescription.
2. All prescriptions for Schedule 2 and 3 CDs (except temazepam*) must be indelible and clearly include:

- Patient's full name, address (and age for children<12)
- Drug name and form, even if only one form exists
- Drug strength (if more than one strength exists)
- Full dose. This should state the number of dosage units (eg tablets, patches) or quantity of medication (eg dose in mg) to be used on each occasion. Instructions such as 'as directed', 'take weekly' and 'bd' are not sufficient
- Total quantity of the preparation, or the number of dosage units to be supplied, in both words and figure
- For instalment prescriptions, directions specifying the amount of the instalments that may be dispensed and the intervals to be observed when dispensing
- The words 'for dental treatment only' if issued by a dentist
- Prescriber's usual signature (handwritten), date and address (these may be computer generated).

*Temazepam prescriptions need only comply with the requirements for Prescription Only Medicines.

3. Private prescriptions for patients for **all** Schedule 2 and 3 CDs must be on a PCD1 form (available from BSO) and include the prescriber's unique identification number.

Action for Pharmacists:

1. The legality of the prescription must be checked prior to dispensing.
2. Community pharmacists can now supply CDs against some prescriptions with a minor technical error but only where the prescriber's intention is clear. The only changes permitted are:

- Minor typographical errors or spelling mistakes
- The total quantity in words, or figures, may be added where one or other, but not both, has been omitted.

Action for Prescribers and Pharmacists:

1. Emergency supplies of Schedule 2 and 3 CDs are not permitted; this includes faxed prescriptions. (Exception: phenobarbital for the treatment of epilepsy).
2. Dispensing of Schedule 2 and 3 CDs is not permitted using the Repeat Dispensing process.
3. Prescribers and pharmacists should be familiar with arrangements for obtaining urgent items (e.g. CDs for terminally ill patients) at weekends and during Out of Hours.

Avoid Mix-up in Supply of Controlled Drugs to Patients

Several incidents have been reported where the patient has received an incorrect supply of their CD medication. Examples include:

- **Standard-release preparation dispensed when the modified-release was intended**
- **Double supply of daily methadone to a drug misuser**
- **Incorrect strength prescribed or dispensed**
- **Delivery to the wrong patient.**

Action for Pharmacists:

1. It is good practice for a second member of staff to be involved in the dispensing process.
2. The original prescription should always be referred to in the dispensing, checking and handing-out processes (including owings); the previous PMR should not be relied upon.
3. Opioid doses that may potentially be harmful to an opioid-naive patient should be double-checked. If the patient and/or opioid dose are not familiar, the intended dose should be confirmed eg by consulting the patient medication record, patient or prescriber.
4. Increased vigilance should be applied to installment prescriptions. This is especially important at potentially complicated times such as bank holidays.
5. A risk assessment should be carried out prior to dispensing CDs into compliance aids e.g. medication for breakthrough pain or medicines that are unstable in a compliance aid are not suitable for a MDS.
6. Patients or carers should be encouraged to collect CDs directly from the pharmacy. Where collection and delivery schemes operate e.g. to housebound patients, CDs should be stored securely during transit and a robust audit trail should be in place to account for the safe delivery from the pharmacy to the patient.

Action for Prescribers and Pharmacists:

1. Certain CD preparations should be prescribed by brand name to ensure continuity of treatment. e.g. opioid patches and morphine sulphate preparations (Refer to HSCB Generic Exceptions List, November 2011). If a modified release medicine is written generically, the pharmacist should confirm the previous brand.
2. Staff should be familiar with the HSCB Medicines Safety Alert on Prescribing and Dispensing of CDs. All HSCB medicines safety alerts can be found at:
   http://www.hscboard.hscni.net/medicinesmanagement/index.html