



Department of
**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

All GP Practices
All Community Pharmacy Practices
Directors of Pharmaceutical Services of Boards
Trust Pharmacy Managers
Directors of Nursing (Board)
Directors of Primary Care Boards
NICPPET
Medical Information Service (Royal)

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CPh1/06

3 January 2006

Dear Colleague

AMENDMENTS TO THE MISUSE OF DRUGS REGULATIONS (NORTHERN IRELAND) 2002

Detailed below are changes to the above Regulations which are due to come into effect on **16 January 2006**. The changes cover a number of areas:

- Handwriting requirements
- Electronic record keeping
- Preservation of records
- Extended formulary nurse prescribing
- Supply of ascorbic acid to addicts
- Cocaine preparations

Controlled Drug Prescriptions

The requirement that Controlled Drug prescriptions (except prescriptions for Schedule 4 or 5 CDs, or temazepam) should be written in the prescriber's own handwriting has been removed. Prescriptions must still be written so as to be indelible and other prescription requirements (eg, to express the total quantity in both words and figures and state the form of the preparation) still apply, but only the signature now needs to be handwritten by the person authorizing the prescription. All other details on CD prescriptions, including the date, can be computer generated. This change also permits the use of stamps and allows other people to write the body of the prescription and means that prescribers no longer need to have a handwriting exemption.

Controlled Drugs Registers

The definition of a Controlled Drug register has been amended to include a computerised system which complies with specified best practice guidance. This means that it is now permissible to maintain a computerised CD register provided that certain requirements are met. The Regulations require that every computerized entry must be attributable and capable of being audited. The computerised register must be accessible from the premises to which it relates and persons authorised under the Misuse of Drugs Act (eg the Department's inspectors) are able to request that a copy of the register, in its computerised or other specified form, be sent to them.

Pharmacists are advised that CD registers may only be held in a computerised form if safeguards are incorporated into the software to ensure all of the following:

- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes

Access control systems should be in place to minimize the risk of unauthorised or unnecessary access to the data and adequate backups must be made. Pharmacists are also advised that arrangements must be made so that inspectors can examine computerized records during a visit with minimum disruption to the dispensing process.

Computerised CD registers should not be maintained unless you can be satisfied that the above requirements (and any future guidance that may be issued) can be adhered to.

Preservation of Records

Registers, requisitions, orders and private prescriptions for Controlled Drugs must be preserved for two years. The regulations have been amended to allow the information contained in these records to be preserved in the original paper form, or as a copy on computer. As with computerized CD registers, pharmacists need to ensure that, where copies of requisitions, orders and private prescriptions are held on computer, safeguards are in place to ensure the data cannot be altered at a later date, that all data can be recalled for audit purposes, that adequate backups are made and that systems are in place to minimise the risk of unauthorised access to the data.

Extended Formulary Nurse Prescribing

Amendments have been made to the Regulations to extend the range of Controlled Drugs that extended formulary nurse prescribers can prescribe, supply or administer. Extended formulary nurse prescribers will be able to prescribe, administer or supply the following CDs, solely for the medical conditions indicated:

- Diamorphine, diazepam, lorazepam, midazolam, morphine or axycodone for use in palliative care
- Buprenorphine or fentanyl or transdermal use in palliative care
- Diamorphine or morphine for pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief

- Chlordiazepoxide hydrochloride or diazepam for treatment in initial or acute alcohol withdrawal symptoms
- Codeine phosphate, dihydrocodeine tartrate or co-phenotrope (no restrictions on medical conditions)

Extended formulary nurse prescribers will not be authorized to prescribe, administer or supply these drugs for these conditions until corresponding changes have been made to Medicines Act legislation.

Ascorbic Acid

Ascorbic acid has been added to the list of drug paraphernalia that specified persons (including pharmacists) can supply to illicit drug users for the purpose of administering or preparing controlled drugs.

Cocaine Preparations

Preparations containing not more than 0.1 per cent cocaine are no longer exempt from prohibitions on import, export and possession.

If you have any queries concerning these matters please contact Pharmaceutical Advice and Services Branch at 028 90523348 or 028 90520768.

Yours sincerely

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