Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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Circular 015/17 20 April 2017.

Re: Misuse of Drugs Regulations 2017.

Dear Healthcare Professional,

Please find enclosed a communication from the Department of Health in relation to the Misuse of Drugs Regulations 2017 which are anticipated to come into force in May 2017.

Yours faithfully,

Anne Marie Hoey

Anne Marie Hoey,
Primary Care Reimbursement & Eligibility.

An Roinn Sláinte
DEPARTMENT OF HEALTH

12 April 2017

re: Misuse of Drugs Regulations 2017

Dear Healthcare Professional,

The purpose of this letter is to bring to your attention imminent changes to the regulations relating to controlled drugs. Significant changes to the prescribing and dispensing of benzodiazepines and 'z-drugs' will come into force with the new Misuse of Drugs Regulations 2017. **It is anticipated that the new Regulations will come into force on 4 May 2017**. Healthcare professionals are asked to prepare for changes to their practice in anticipation of their introduction. Once signed, the Regulations and associated Orders will be available on www.irishstatutebook.ie and there will also be a link via the Department of Health website www.health.gov.ie .

Background

On 27 July the Misuse of Drugs (Amendment) Act 2016 was passed by the Oireachtas. The primary purpose of the Act is to protect public health by bringing certain substances which are open to misuse, and known to be traded on the illicit market, under the scope of the Misuse of Drugs legislation, thereby aiding the law enforcement activities of An Garda Síochána. In addition, it will allow Ireland to fulfil its obligations and to control new psychoactive substances in accordance with EU Directives and international drug control

Subsequent to this Act new Misuse of Drug Regulations are required to allow legitimate users (e.g. health professionals, patients with a prescription) to continue to possess certain controlled drugs. The changes made in the new 2017 Regulations were included in a 2013 public consultation; however it was not considered appropriate to progress with the majority of the amendments proposed in 2013 at this time.

The most significant effect of the new Regulations is in relation to benzodiazepines and 'z-drugs'. The new Regulations contain a new Schedule 4 Part 1 and the restrictions in place on possession of controlled drugs will apply to controlled drugs listed in this new part. Most benzodiazepines will now be in Schedule 4 Part 1 of the new Regulations, as will the 'z-drugs' zopiclone, zolpidem and zaleplon. Temazepam and flunitrazepam will remain in Schedule 3.

Additional import/export controls and prescription requirements will apply to the drugs listed in Schedule 4 Part 1. The main changes to the 'Form of Prescription' and 'Supply on Prescription' are listed in Appendix I to this letter.

Tús Áite do Shábháilteacht Othar
Patient Safety First

hi Healthy Ireland

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It should be noted that the new Regulations do not require drugs in Schedule 4 Part 1 to be stored in a safe.

Nurses and Midwives

It is necessary to update the Misuse of Drugs Regulations following the enactment of the Nurses and Midwives Act 2011. The 2017 Regulations update the list of controlled drugs and the clinical situations in which those controlled drugs may be prescribed by nurse or midwife prescribers.

Implementation

Appendix I is not an exhaustive list of all the changes contained within the Misuse of Drugs Regulations 2017. Healthcare professionals should familiarise themselves with all the provisions of the new Regulations.

Benzodiazepines may be prescribed safely in the short-term and are effective treatments for anxiety, insomnia and some forms of epilepsy and spasticity, among other conditions. However ordinarily, benzodiazepines and z-drugs are only indicated for short term use.[1] Such medications should ordinarily be used for short periods of treatment to avoid patients becoming addicted to these useful but challenging medicines.

The amendments to the Regulations, in combination with the individualised prescribing reports issued by the PCRS (last issued November 2016), should afford practitioners an opportunity to review patients receiving such medications. The additional prescription requirements should offer an opportunity to make brief interventions with these patients. Such brief interventions have been shown to be of value in reducing prescription usage.

In order to minimise the impact of these changes to patients and practitioners, prescriptions issued before the coming into force of these new regulations will continue to be valid. Prescriptions issued on or after 4 May 2017 **must** comply with the new prescription requirements.

Yours faithfully,

Eamonn Quinn

Pharmacist
Medicines, Controlled Drugs and Pharmacy Legislation Unit

[1] http://health.gov.ie/wp-content/uploads/2014/04/Benzodiazepines-Good-Practice-Guidelines.pdf

APPENDIX I

Changes to the 'Form of Prescriptions' and 'Supply on Prescription' for Schedule 2 and 3 controlled drugs

The **name and address of the patient** or in the case of a veterinary prescription, the name and address of the person to whom the controlled drug is to be delivered**, no longer has to be handwritten.** (NB addressographs or adhesive labels will not fulfil the requirement that this information must be indelible.)

However a number of **additional elements** are required on the prescription in order to aid identification and ensure clarity:

- Inclusion of the **first name of the prescriber** on the prescription
- Inclusion of the **prescriber's registration number** on the prescription
- The **name of the controlled drug** to be prescribed must be included on the prescription i.e. either the common/generic name or the proprietary/brand name of the preparation

Additional prescribing requirements for Schedule 4 Part 1 controlled drugs

The specific criteria to be included on a prescription for Schedule 2 and 3 controlled drugs will now also apply to controlled drugs in Schedule 4 Part 1 i.e.

- Name of the drug (either the common/generic name/INN or proprietary/brand name)
- Dose
- Pharmaceutical form
- Strength (where appropriate)
- Total quantity of controlled drug to be dispensed **written in both words and figures**

However for controlled drugs in **Schedule 4 Part 1 only, these will not be required to be handwritten.** The requirements for these specific criteria to be specified in the prescriber's handwriting will also not apply to prescriptions for Methadone issued on the appropriate prescription form.

Controlled drugs in Schedule 4 Part 1 will not have to be first dispensed within 14 days of the date written on the prescription and may be repeated. Where a repeat prescription for a Schedule 4 Part 1 controlled drug is dispensed the prescription must be endorsed by the pharmacy and the following details recorded on the prescription:

- The quantity of each controlled drug supplied
- The date on which the supply was made
- The name and address of the pharmacy

Pharmacists are required to keep a copy of the prescription and any endorsements made on the prescription. Where the prescription has been exhausted, the prescription must be endorsed and retained on the premises for two years.