

THE MISUSE OF DRUGS REGULATIONS 2015

CPD ARTICLE

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CPD ARTICLE

Controlled drugs legislation being introduced in 2015 makes a number of amendments to the Misuse of Drugs Regulations 2001 and subsequently the Misuse of Drugs Act 1971.

The Misuse of Drugs (Amendment) (No 2) Regulations 2015 further strengthens the safe management of controlled drugs and the accountability for their supply following the Shipman enquiry. This module focuses on those changes likely to impact on pharmacy practice.

These legislative changes are applicable to England, Wales and Scotland and will be implemented at various stages throughout 2015. The amendments will also be made in Northern Ireland but under separate legislation and timetables.

1 JUNE 2015

TEMAZEPAM

As of 1 June the exemption from CD prescription requirements is removed for temazepam, a schedule 3 controlled drug (CD No Reg). Prescriptions for temazepam will now be required to meet the full prescription requirements for Schedule 2 and 3 controlled drugs.

In addition to the standard requirements of an appropriate date and prescriber's signature, temazepam prescriptions must now state:

- The formulation, i.e. tablets, oral solution
- The strength of formulation, as there is more than one possible strength
- A clearly defined and legally acceptable dose - this must include a number of tablets or milligrams or millilitres, as well as a frequency. 'When required' or 'as directed' without a quantity is not sufficient.
- The total quantity in both words and figures. The Home Office has stated that this should be expressed as a number of dosage units i.e. 10 (ten) tablets. It can also be expressed as a multiplication of two numbers e.g. Two (2) packs of twenty-eight (28) tablets.

Where either the words or figures (but not both) are missing from the prescription and where the prescriber's intentions are clear the pharmacist can annotate the prescription to include both quantities.

There is no change to the record-keeping requirements for temazepam; an entry in the CD register is NOT required. Temazepam remains subject to safe custody requirements.

View our summary table of [CD prescription requirements](#) for schedule 2 and 3 drugs.

ELECTRONIC PRESCRIBING

The electronic prescribing of schedule 2 and 3 controlled drugs will now be permitted where the Electronic Prescribing System (EPS) is used. Previously only schedule 4 CDs were authorised under the EPS. Private prescribing of controlled drugs is permitted provided it is done within the EPS structure.

Whilst the authorising legislation is now in place there is currently no facility within EPS to prescribe the total quantity of drug in both words and figures. Software updates will be necessary for the EPS and for PMR systems in order to implement this facility. At the time of writing there is no indication as to when these updates will occur.

PARAMEDICS AND AMBULANCE TRUSTS

Paramedics are currently permitted to parenterally administer a number of prescription only medicines, including some controlled drugs, in the course of their practice. The authority to administer medicines depends on the ability to requisition them in the first place, a process that was previously ambiguous. The 2015 regulations strengthen the current provisions for paramedics to obtain controlled drugs in two ways.

Under the 2001 Regulations ambulance trusts did not have the authority to possess or supply controlled drugs to their employees. The 2015 Regulations provide authority to “organisations providing ambulances services” to possess and supply controlled drugs in schedules 2 to 5 to employees of the Trust. The authority does not extend to private ambulance services who will continue to need a licence for controlled drugs possessed and supplied by the Service.¹

The new provision enables ambulance trusts to order, stock and supply drugs to paramedics and other healthcare professionals employed by them. The intention is to provide a robust audit trail for controlled drugs used within this sector and to reduce the risk of diversion.

In practice this change means that paramedics will be less likely to need to requisition their own controlled drugs. Up until now the authority to administer CDs has implied the authority to requisition them and best practice has dictated that a written signed order is provided to the supplying pharmacy.

The 2015 Regulations introduce a requirement for paramedics to issue a written requisition in order to obtain supplies of controlled drugs. This effectively turns best practice into legislation.

Some ambiguity still remains with the supply of CDs to paramedics; there is a discrepancy between the list of drugs paramedics are authorised to administer under a Medicines Act exemption and those that are clinically recommended for use in practice. The exemption to the Medicines Act for paramedics lists a range of POMs that can be administered in the course of their practice, and hence can be requisitioned.² The only controlled drugs listed are

¹ Home Office Explanatory Memorandum to The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015; SI 2015 No. 891; accessed online on 6/6/2015 at http://www.legislation.gov.uk/ukxi/2015/891/pdfs/ukxiem_20150891_en.pdf

² Medicines and Healthcare products Regulatory Agency; Exemptions from Medicines Act restrictions (Archived content); Paramedics; accessed online on 6/6/15 at

diazepam 5mg/ml emulsion for injection (schedule 4) and morphine sulphate solution for injection (schedule 2).

Given the new authority to ambulance trusts described above we would advise that requests from paramedics for all controlled drugs other than morphine and diazepam 5mg/ml emulsion be referred back to their employer.

PHYSIOTHERAPISTS AND CHIROPODISTS

The 2015 Regulations aim to improve access to medicines and improve health outcomes for patient by authorising physiotherapist and chiropodist independent prescribers to prescribe a limited range of controlled drugs to patients. These are predominantly by oral administration for the treatment of organic disease or injury; prescribing for the purposes of treatment of addiction is not permitted.

Physiotherapist independent prescribers are able to prescribe the following controlled drugs for the treatment of organic disease or injury:

- Diazepam (oral)
- Dihydrocodeine (oral)
- Fentanyl (transdermal)
- Lorazepam (oral)
- Morphine (oral and parenteral)
- Oxycodone (oral)
- Temazepam (oral)

Chiropodist/podiatrist independent prescribers are able to prescribe the following controlled drugs for the treatment of organic disease or injury:

- Diazepam (oral)
- Dihydrocodeine (oral)
- Lorazepam (oral)
- Temazepam (oral)

Prescriptions must satisfy the additional requirements for prescribing of schedule 2, 3 and 4 drugs.

MIDWIFE SUPPLY ORDERS

Midwives are currently permitted to requisition and supply controlled drugs through the use of a midwife supply order. Midwives are now required to include the name of the person to whom the drug is to be administered or supplied, effectively making the order a patient specific direction. Community pharmacists are unlikely to encounter this type of requisition form.

<http://webarchive.nationalarchives.gov.uk/20150122075153/http://mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/Paramedics/index.html>

1 JULY 2015

VETERINARY PRESCRIBING

As of 1 July 2015 veterinary prescriptions for Schedule 2 and 3 controlled drugs must include the Royal College of Veterinary Surgeons registration number of the prescriber.

30 NOVEMBER 2015

A number of legislative changes are scheduled for later in the year, becoming effective from 30th November 2015. For completeness they will be discussed here but please be advised that the provisions may or may not be in place at the time of reading.

STANDARDISED REQUISITION FORMS

The Shipman enquiry recommended that all purchases of schedule 1, 2 or 3 controlled drugs by healthcare professionals should be monitored. In order to implement this recommendation standardised requisition forms were introduced in 2006 with a requirement that they be submitted to NHSBSA. Their use was not mandatory. Current data from NHSBSA suggests that around half of all CD requisitions do not use the standardised form.¹

The 2015 regulations make the use of the standardised CD requisition forms mandatory for all healthcare professionals:

- England – FP10CDF
- Wales – WP10CDF
- Scotland – GP10A / CDRF
- Northern Ireland – HS21S

As of 30th November any requisition for a schedule 1, 2 or 3 CD not written on the above form cannot be processed. Healthcare professionals can obtain supplies of the correct form from their local health board in Scotland and Wales or the commissioning support unit of their Area Team in England.

Requisitions for supply of CDs for use in prisons and 'end-of-life' hospices are exempt from this requirement.

KETAMINE

Following concerns over the recreational use and abuse of ketamine it was reclassified as a Class B controlled drug in 2014. To further regulate its supply ketamine will also be reclassified from a schedule 4 to a schedule 2 CD. Prescriptions must therefore meet the additional requirements of schedule 2 drugs. Exemptions are in place to allow for the continued use of ketamine by specified healthcare professionals under Patient Group Directions, for example in the treatment of addiction.

SUMMARY

A number of changes to CD legislation introduced in the UK in 2015 will impact on the practice of pharmacy.

We have updated the Numark CD SOPs to reflect the new legislation and we would advise all members to ensure their own SOPs are up to date. CD SOPs can be downloaded from NumarkNet here: <https://www.numarknet.com/download/112?show=8>

Further details of the changes can be found in the Home Office Circular 019/2015: Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2015 (S.I. 2015/891). This document also provides links to the legislation itself and the explanatory memorandum. <https://www.gov.uk/government/publications/circular-0192015-a-change-to-the-misuse-of-drugs-regulations-2001/circular-0192015-misuse-of-drugs-amendment-no-2-england-wales-and-scotland-regulations-2015-si-2015891>

DOCUMENT INFORMATION

Document title:	CPD_The Misuse of Drugs Regulations 2015
Document reference:	REF
Prepared by:	Michael Stewart
Signature:	
Date of preparation:	08/06/2015
Effective from:	15/06/2015
Version:	1.0
Date of next review:	15/06/2015

Version	Date	Author	Notes
1.0	08/06/2015	Michael Stewart	FINAL