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Guidance for the Handling of Tramadol in Health and Justice Residential Settings in Wales

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Author: Rosemary Allgeier

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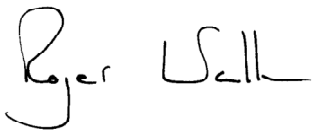
Foreword

Tramadol is an opioid analgesic medicine used in the relief of moderate to moderately severe pain. In common with other opioids it is liable to misuse and can be fatal in overdose. Following growing concerns around misuse, harm and fatalities tramadol was re-classified as a Schedule 3 Controlled Drug in 2014.

"Guidance for the handling of Tramadol in Health and Justice Residential Settings in Wales" takes account of the legislative re-classification of tramadol as a Schedule 3 Controlled Drug and provides guidance on good professional practice in residential health and criminal justice settings. The guidance covers all aspects of the handling and supply of tramadol to ensure suitable levels of security, the supervised administration of tramadol not 'in-possession' and prescribing where clinically appropriate.

This guidance will be a valuable resource to support policy and improve practice in the prescribing and handling of tramadol.



Professor Roger Walker

Chief Pharmaceutical Officer for Wales

Guidance on the handling of Tramadol in Health and Justice Residential Settings in Wales

Adapted from:

Guidance for the Handling of Tramadol in Health and Justice Residential Sites (Guidance: for England only) NHS England: Public Health, Armed Force and Health and Justice Commissioning (Commissioning Directorate) June 2014

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The author thanks all those who kindly gave their time to send their comments during the development of this guidance. A list of these contributors is available on page 13.

The author also thanks Denise Farmer, Chair of the Tramadol Handling Task and Finish Group (England) for sharing knowledge and experience on this topic.

Abbreviations

BNF	British National Formulary
CD	Controlled Drug
CDAO	Controlled Drugs Accountable Officer
IT	Information technology
MAR	Medication administration record
MDT	Mandatory Drug Testing
MHRA	Medicines and Healthcare products Regulatory Agency
NLRS	National Learning and Reporting System
NHS	National Health Service
PGD	Patient Group Direction
POM	Prescription only medicine
SI	Statutory Instrument
SPC	Summary of Product Characteristics
WDA(H)	Wholesale dealer's authorisation for medicines for human use

Contents

1 Purpose

This document provides guidance to health and justice healthcare and pharmacy service providers, health and justice commissioners and Controlled Drugs Accountable Officers about the expected handling of tramadol in **residential** health and justice sites in Wales in view of its re-scheduling to a Schedule 3 Controlled Drug as a result of changes in the Misuse of Drugs Act (1971).

The guidance informs stakeholders of the expectations of how this change should be operatrionalised to meet the legislative requirements and provide safe access to this medicine by patients.

Note:

- Temporary secure environments (such as police custody) are outside the scope of this guidance.

2 Background

On 10 June 2014 amendments to the Misuse of Drugs Act 1971 came into force. These amendments included the reclassification of tramadol hydrochloride (referred to as tramadol hereafter) as a Controlled Drug.

The 2014 Order (**SI 2014/1106**) came into force on **10th June 2014** and is available at www.legislation.gov.uk/uksi/2014/1106/contents/made.

Tramadol is a Class C Schedule 3 Controlled Drug (CD) but exempted from safe custody requirements (CD No Register POM).

In summary, tramadol is:

- Controlled as a Class C drug.
- Listed as a Schedule 3 drug under the Misuse of Drugs Regulations 2001.
- Subject to full prescription writing requirements under Regulation 15 when prescribed in healthcare.
- Exempt from safe custody requirements.

Table 1: Summary the effect of legislative changes for tramadol

Legal implications for tramadol	
Designation as a CD from 10th June 2014	Schedule 3 (CD No Reg POM)
Safe custody regulations apply	No
CD prescription requirements	Yes
Prescription valid for	28 days
Prescription is repeatable (e.g. 'repeat x 3')	No
Emergency supply	No
CD Requisition necessary	Yes
Requisition to be marked by supplier	Yes
Denature before disposal	Yes

Note:

- This legislation has not changed the requirements for temazepam.
- SI 2014/1106 included specification changes to lisdexamfetamine, zopiclone and zaleplon. These changes are outside the scope of this guidance. Health and justice healthcare and pharmacy service providers should agree local arrangements for any changes made in handling these medicines based on local risk assessments.

3 Implications for tramadol handling

Current prison healthcare guidance[1] recommends that Schedule 3 CDs in secure settings are handled in the same way as Schedule 2 CDs. This means they require safe custody (stored in a CD cupboard), secure transportation within the secure environment and a written record in a CD register (or equivalent on prison wings) of every receipt or supply of the medicine to the patient.

The re-scheduling of tramadol as a Schedule 3 CD (without safe custody requirements) has operational implications for prisons and other health and justice residential sites such as Young Offender Institutions and Secure Children's Homes in Wales.

4 Actions and expectations for handling tramadol

The actions and expectations of tramadol handling are described using the medicines trail [2] approach to the pathway for the handling of medicines described in Sections 5 to 13 of this guidance.

In preparation for the implementation of the expectations healthcare providers should consider completing an audit of current tramadol prescribing and handling in order to inform the planning of medication review and operational handling changes required. The All Wales Therapeutics and Toxicology Centre has produced *Tramadol Educational Resource Materials* to encourage the review and promotion of appropriate prescribing of tramadol.[3]

It is suggested that the implementation of these changes is overseen and led by the relevant medicines management committee at the health and justice site.[4] Implementation of these expectations also requires revision and amendment of Controlled Drug Standard Operating Procedures.

5 Prescribing

5.1 Prescriptions for tramadol

In line with other Schedule 3 CDs **all** tramadol prescriptions need to comply with the controlled drug prescription writing requirements and good practice. Prescriptions for tramadol must contain the following details as shown in Table 2, and written so as to be indelible, (e.g. handwritten in ink, typed or computer-generated).

Table 2: Summary of legal and good practice for tramadol prescriptions

1.	The patient's full name (prison number and surname if in prison), address (within the health & justice site) and, where appropriate, age.
2.	The patient's photograph should be attached to the front of the prescription chart. This is not a legal requirement but is good practice within the health and justice setting.
3.	The name and form of the drug, even if only one form exists. The abbreviations *tabs.* and *caps.* are acceptable.
4.	The strength of the preparation, where appropriate (if more than one strength exists).
5.	The dose to be taken.
6.	The total quantity of the preparation, or the number of dose units to be supplied, **in both words and figures.**
7.	Signed by the prescriber with their usual signature (this must be handwritten including computer-generated paper prescriptions) and dated by them (the date does not have to be handwritten).
8.	The date can be either the date of signing **or** the date the prescriber wishes the prescription to start. The prescription will be valid for dispensing for 28 days from the date stated.
9.	The address of the prescriber must be stated on the prescription.

5.2 Clinical reviews of patients prescribed tramadol

- Re-scheduling has provided an opportunity for full clinical review of patients prescribed tramadol in line with current guidance.[5,6]
- Prescriptions for tramadol should be prescribed as acute and non-repeatable items. Prescribers should consider more regular review of patients on tramadol **at least every 3 months** as is recommended for other Schedule 3 CDs such as buprenorphine.[7]

5.3 Prescribing appropriate formulations

- F**or medium to long term i**ndications the usual formulation of tramadol prescribed should be 12-hourly or 24-hourly preparations. There is no clinical advantage of short-acting preparations of tramadol for long-term indications[8,9,10] and such patients should have their tramadol supply reviewed so that short acting preparations are switched to the longer acting versions where possible. Use of modified release preparations that require once or twice daily dosing can ensure that optimal treatment is provided.[5]
- Where short-acting tramadol is necessary, providers need to ensure that the dosage interval between supervised administrations is within the expected time periods as detailed in the relevant Manufacturer's Summary of Product Characteristics (SPC) and the British National Formulary.
- Alternatives to tramadol for acute pain may be more practical given the in-possession expectations for tramadol (see section 9).

6 Requisitioning (ordering of Schedule 3 CD stock) and stock supply

6.1 In-house prison pharmacies

- Where prisons in Wales have in-house pharmacies, the pharmacist is responsible for ordering stock supplies of tramadol from a pharmaceutical wholesaler in the same manner as hospital or community pharmacies. Stock for prison wings / treatment areas are ordered from the pharmacy using a hospital style requisition book or equivalent. This arrangement mirrors the same procedures established in secondary care hospitals.[11]
- The requirements to mark and send the requisition to NHS Wales Shared Services Partnership do not apply when supply is made by a prison pharmacy to prison wings / treatment areas within the prison. The pharmacy must retain the requisition for 2 years.[11]
- If the healthcare provider is required to and, already has a licence to possess stock supplies of Schedule 3 CDs such as buprenorphine, adjustments to the licence are not needed.
- If the in-house pharmacy is a different legal entity to the healthcare provider, the pharmacy may be affected by the wholesale dealer and CD supply licensing requirements. The pharmacy service provider should take action to confirm whether a wholesale dealer's authorisation for medicines for human use WDA(H) and / or a license to supply Schedule 3 CDs is required.

6.2 Community pharmacies

- Prisons in Wales which have arrangements in place for supplies of medicines through a registered community pharmacy do not, at the time of publication of this guidance, order stock supplies of tramadol. The following would apply should the situation change in future:
    - Ordering of stock supplies of tramadol has to be via a legally signed CD requisition as detailed in the Misuse of Drugs Regulations and related guidance.[11,12] In residential health and justice settings this means that the requisition needs to be signed by a doctor or a pharmacist who is employed or engaged by the establishment.

- Signed requisitions from NHS commissioned services do not need to be on the WP10 CDF requisition form or returned to NHS Wales Shared Services Partnership. Community pharmacies must retain the requisition for 2 years.
- Community pharmacy service providers supplying residential health and justice sites with stock of CDs should have a licence to supply Schedule 3 CDs. Those already supplying residential health and justice sites with stock supplies of buprenorphine will not need adjustments to the CD supply licence.

- **Note:** Community pharmacy service providers supplying stock medicines to residential health and justice sites that do not already have an MHRA WDA(H) should take action to confirm whether this is required.

7 Dispensing of tramadol prescriptions by pharmacy service providers

- Pharmacy service providers expect prescriptions for tramadol to meet regulatory requirements for prescription writing as detailed in section 5.1. Any prescription not meeting these requirements is likely to be returned for adjustment prior to supply and may cause delays in treatment.
- Pharmacy service providers will only dispense from the original hand-signed CD prescription. Healthcare service providers should therefore copy and/or scan this original and retain a local copy for reference and continuity of care (see section 12).
- Where prisons in Wales have arrangements in place for dispensing of medicines through a registered community pharmacy using WP10 prescription forms, prescriptions for tramadol need to be written on these forms.

8 Storage and transport of tramadol on-site: stock and dispensed named patient supplies

8.1 Storage of tramadol

The security of storage relating to stock supplies of tramadol should be handled differently to named patient supplies in order to:

- Minimise the risk of medication errors, and the overcrowding that would occur should all supplies of tramadol be stored in CD cupboards.
- Acknowledge the need to have a robust audit trail for tramadol, especially stock supplies in prisons as is the case for buprenorphine.

On this basis tramadol supplies should be stored in the following way in prison wing/treatment areas (see Tables 3 and 4):

Table 3: Storage of named patient supplies of tramadol on prison wings / treatment areas

Storage of labelled named patient supplies of tramadol:
• These are medicines dispensed by a pharmacy from a written CD prescription. The current advice concerning the use of named patient medication for the majority of care[4] **continues to apply for tramadol**. • The tramadol should be stored along with the other named patient medication the patient is taking and **not stored in a CD cupboard**. (See section 10 for audit/reconciliation recommendations)

Table 4: Storage of stock supplies of tramadol on prison wings / treatment areas

Storage of stock supplies of tramadol:
• There are certain circumstances where stock tramadol needs to be administered using stock supplies from prison wings / treatment areas, for example for supply of initial doses, transferred prisoners who arrive without their own supply, or for out of hours/urgent doses. (This includes any over-labelled stock). • Tramadol stock supplies need to be kept in the CD cupboard and receipt and supply recorded as for buprenorphine (see Section 10).

8.2 Transport of tramadol

- It is expected that supplying pharmacies will separate out supplies of tramadol for stock purposes from labelled named patient dispensed tramadol.
- When tramadol is transported within a residential health and justice site, local arrangements should be in place to minimise security risks as detailed in Prison Service Instruction IDTS 2010/45.[1]

9 Administration and supply:

9.1 Expectation to administer tramadol not in-possession

- It is expected that in **all** residential health and justice sites tramadol is supplied **not in-possession,** with administration of tramadol to prisoners carried out by appropriate healthcare practitioners (see Section 9.2). Thus there is continuity of practice when patients prescribed tramadol enter custody or are transferred to another heath and justice site.
- Residential health and justice sites need to consider the operational implications, in particular the possible increase in medicines treatment sessions and security supervision, based on their current and expected prescribing of tramadol. This requires partnership working with prison governors (or equivalent in other settings) and their representatives.
- All residential health and justice sites, where tramadol has been allowed in-possession, need to review and amend their operational arrangements to meet the expectations within this guidance.

9.2 Expectation to administer tramadol under supervised consumption

- As for other Schedule 3 CDs, tramadol must be administered under supervised consumption using a process that provides the same level of security and minimises the risks of diversion as those used to administer opioid substitution therapy and expected as per PSO 3550.[13] Local procedures should identify who may administer tramadol.

9.3 Patient Group Directions

- Patient Group Directions (PGDs) for tramadol are no longer permitted as tramadol is not listed in the Misuse of Drugs Regulations as a CD that can be supplied under a PGD.

10 Recording of tramadol transactions

10.1 Labelled named patient supplies

- Doses administered must be recorded on the electronic or manual medicines administration system as for other medicines. Local CD standard operating procedures need to provide assurance (via audit or reconciliation of the patient labelled medicines) that patient labelled tramadol supplies are not subject to unexplained loss or gain.

10.2 Stock supplies

- Recording of stock tramadol within healthcare, wings (and other treatment rooms) and on-site pharmacies should be made in a CD record book with documentation of the elements required for a Schedule 2 CD register. This brings the handling of tramadol stock in line with the requirements for buprenorphine in Prison Service Instruction IDTS 2010/45.[1] (This includes any over-labelled stock).

11 Prescription retention

- Where prisons in Wales have in-house pharmacies, dispensed prescriptions for tramadol must be retained by the dispensing pharmacy for 2 years.
- Where prisons in Wales have arrangements in place for dispensing of medicines through a registered community pharmacy using WP10 prescription forms, dispensed prescriptions for tramadol should be sent to the NHS Wales Shared Services Partnership.
- In circumstances where tramadol needs to be administered to patients using stock supplies from prison wings / treatment areas, the original hand-signed prescriptions must be retained by the healthcare provider (by the pharmacy if this service is in-house) for 2 years.
- Where residential health and justice sites use a clinical IT system, tramadol prescriptions should be scanned into the system to support continuity of care and easy access to a copy of the original hand-signed prescription by healthcare staff.
- **Note:** Patient medication administration records (MARs) are considered to be part of patients' health records and advice should be sought from the local health board on the period of time for which MARs should be retained.

12 Continuity of care on transfer

It is well recognised that there are ongoing issues with the transfer of information and medication for patients prescribed Schedule 2 and 3 CDs. The re-scheduling of tramadol means that these issues could result in the risk of delayed and omitted doses of tramadol. This guidance provides an opportunity to remind healthcare providers in all residential health and justice sites in Wales about the expectations of transferring patients taking Schedule 2 and 3 CDs.

12.1 As tramadol will normally be provided as a named patient supply without the need for CD storage, a patient's supply of tramadol can be transferred with their other medicines on transfer as expected for all other named CD medicines.

12.2 Providers need to revise transfer documentation to include tramadol in the list of medicines that transport contractors have to sign for. This provides a robust audit trail for the sending and receiving establishment. In addition to the supply of tramadol, the following information needs to be provided to the receiving establishment on transfer (and is the expectation for all Schedule 2 and 3 CDs):

- A copy of the hand-signed current tramadol prescription (either a hard copy or for prison transfers a scanned copy on the clinical IT system).

- Information that shows the patient has received doses up to 5 days before transfer. This can be evidenced by the manual medicines chart (original or copy) or a print out of the e-administrations that have taken place. This provides the receiving establishment with assurance that recent doses have not been missed.

12.3 When patients are released from residential health and justice settings the requirements for supplying medicines on release is unchanged. Systems should be in place for ensuring that a patient has, or is able to access, a supply of medicines on release.[14] Wherever possible, a patient's GP should be informed so that arrangements can be made for further prescribing. Patients prescribed tramadol need to be able to access continued doses of tramadol. Initial access can be facilitated either by;

- Giving the patients their current named supply or 'take-home' dispensed tramadol, usually no more than 7 days' supply on release, or
- Providing a WP10 prescription (meeting the requirements detailed in Section 5.1) where the release is unplanned[15] and the named supply cannot be accessed prior to release.

12.4 To support transfer of care between residential health and justice settings and hospital care, local healthcare providers are advised to make local agreements with secondary and tertiary care providers in line with transfer of care guidance[14] to:

- Share information in formularies for the management of pain (acute and chronic) to enable the residential health and justice site formulary to be used where possible (e.g. long-acting vs. short-acting tramadol).
- Agree discharge information and follow-up arrangements for acute pain management that enables the clinician at the residential health and justice site to reduce the prescribing of tramadol as soon as possible post-discharge.

13 Disposal of tramadol stock

Tramadol is exempt from Safe Custody requirements. However in residential health and justice settings, disposal of tramadol needs to meet the regulatory requirements for other Schedule 3 CDs and **additional safeguards** to ensure robust handling and minimise the risk of diversion of tramadol in these settings:

All CDs in Schedule 2 and those CDs in Schedule 3 that are subject to safe custody requirements should be placed into waste containers only after the controlled drug has been rendered irretrievable (i.e. by denaturing). Where practicable, CD denaturing kits should be used in order to denature CDs including tramadol. These can be obtained from pharmacy service providers or waste contractors.

13.1 Labelled named patient supplies

- To minimise the risk of supplying the patient returned, out-of-date or obsolete CD to a patient in error, when these are no longer needed, the named patient supply should be moved to the CD cupboard in an area set aside for CD named-patient returns. The details of the tramadol should be entered into a record book used to note down named patient CDs awaiting destruction.
- As soon as possible the named patient supply should be destroyed by a registered professional and a witness with the destruction documented in the record book. This is considered good practice.

13.2 Stock supplies

- Stock awaiting destruction should be separated from current stock but not signed out of the CD stock record. (This includes over-labelled stock).
- Tramadol stock that is expired should be destroyed in the presence of an authorised witness. Providers need to seek advice from their Controlled Drugs Accountable Officer (CDAO) whether within their organisation or health board. .
- Tramadol stock awaiting destruction should be checked as part of routine CD stock reconciliation to ensure it is still accounted for.

14 Related issues

14.1 Mandatory drug testing in prisons

- The National Offender Management Service (NOMS) will trial the inclusion of tramadol in routine mandatory drug testing (MDT) [16], with a view to permanent inclusion. As with all MDT failures, custody staff are expected to refer prisoners testing positive for tramadol misuse to drug treatment providers for assessment.
- It is good practice for prisons and healthcare providers to share information on MDT results so the extent of medication misuse is well understood, and to ensure that prisoners prescribed tramadol (or any other medicine tested for) are not testing negative (indicating they are not taking their medicines).

14.2 Patient safety incidents and prison intelligence reports involving tramadol

- Any incident involving tramadol that is identified via a prison intelligence report (IR) or a healthcare identified patient safety incident should be formally reported using local arrangements and the National Learning and Reporting System (NLRS). Incidents should be reviewed in line with local arrangements.
- In addition, these reports should be included in the submission of incidents to the organisation's CDAO and/or the CDAO in their health board, depending on local arrangements.

15 Implementation Tools

The resources used at HMP Wakefield to implement and support the changes to how tramadol is prescribed and handled, including the transition to long-acting preparations and supplies not in-possession, have kindly been shared by the healthcare team at Spectrum Community Health. The resources are available at:

http://www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Meds-use-and-safety/Service-deliv-and-devel/OffenderHealth/SAFER-PRESCRIBING-ASSESSMENT-REVIEW/?id=788007

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Contributors

Mike Hardy	Head of Offender Health Policy, Welsh Government
Lynzi Jarman	Head of Effective Practice and Innovation Cymru, Youth Justice Board Cymru
Dr Sue Jeffs	Consultant in Anaesthesia, Clinical Lead for Pain Management, and Chair, Medicines and Therapeutics Committee, Aneurin Bevan University Health Board
Hywel Jones	Prescribing Advisor, Prison Pharmacy Lead, Aneurin Bevan Health Board
Lowri Jones	Pharmacist, Focus Healthcare, HMP&YOI Parc
Dr Jake Hard	GP with special interests in prison medicine and substance misuse, and Chair, RCGP Wales Secure Environments Group
Halina Moulton	Pharmacist, Shackleton Pharmacy, High Street, Raglan, Monmouthshire
Louise Noble	Senior Pharmacist, HMP Cardiff
Cathryn Richards	Head of Pharmacy and Independent Prescriber, HMP Swansea
Dana Tait	Community & Custodial Pharmacist and Independent Prescriber