NHS England

Guidance for the Handling of Tramadol in Health and Justice Residential Sites

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Document Status

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

Expectations resulting from the Rescheduling of Tramadol as a Schedule 3 Controlled Drug

First published: June 2014

Prepared by: NHS England Health and Justice Commissioning Clinical Reference Group

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Equality and diversity are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have given due regard to the need to:

- Reduce health inequalities in access and outcomes of healthcare services integrate services where this might reduce health inequalities
- Eliminate discrimination, harassment and victimisation
- Advance equality of opportunity and foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it."

Background and purpose of this document

From June 10th 2014, the Misuse of Drugs Act 1971 (the 1971 Act) and the Misuse of Drugs Regulations 2001 (the 2001 Regulations) have been amended to reclassify certain drugs.

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

These changes include:

- Re-classifying tramadol as a Schedule 3 Controlled Drug but exempted from safe custody requirements.
- Lisdexamfetamine becomes a Schedule 2 Controlled Drug (CD POM)
- Zopiclone and zaleplon are listed in Part 1 of Schedule 4 alongside zolpidem

Table 1 shows in summary the effect of these changes for zopiclone, zaleplon and tramadol:

	Tramadol	Lisdexamfetamine	Zopiclone	Zaleplon
Designation from 10th June 2014	Schedule 3 (CD No Reg POM)	Schedule 2 (CD POM)	Schedule 4 (Part I)	Schedule 4 (Part I)
Safe custody regulations apply	No	Yes	No	No
CD prescription requirements	Yes	Yes	No	No
Prescription valid for	28 days	28 days	28 days	28 days
Address of the prescriber required to be within the UK	Yes	Yes	No	No
Prescription is repeatable (e.g. 'repeat x 3')	No	No	Yes	Yes
Emergency supply	No	No	Yes	Yes
CD Requisition necessary	Yes	Yes	No	No
Requisition to be marked by supplier	Yes	Yes	No	No
Denature before disposal	Yes	Yes	Yes	Yes

N.B. This legislation has not changed requirements for temazepam.

The amendments for Lisdexamfetamine, zopiclone and zaleplon are outside the scope of this guidance. Providers should agree local arrangements for any changes made in handling these medicines based on local risk assessments.

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 settings in the light of its re-scheduling.

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 residential secure environments such as Young Offender Institutions, Immigration Removal Centres (IRC), Secure Training Centres, and Secure Children's Homes.

A Task and Finish Group of key stakeholders was formed to provide a consensus agreement of how tramadol should be handled in prisons and other residential secure environments once it has been legally re-scheduled. This was to ensure that a consistent approach would be adopted by health and justice healthcare providers and to inform commissioners, inspectors (i.e. HMIP, CQC, Home Office) and Controlled Drugs Accountable Officers about tramadol handling expectations in residential secure environments.

Temporary secure environments (such as police custody) are outside the scope of this briefing and any requirement for formal information for these sites will be considered separately.

This document

- Describes the decisions made by the Task and Finish group and the actions that should be taken by health and justice providers to implement these decisions.
- Reiterates key expectations of Controlled Drug handling that now apply to tramadol.

[1] Prison Service Instruction: PSI IDTS 2010/45

Actions and Expectations for handling Tramadol

The actions and expectations of tramadol handling have been considered using the medicines pathway[2] which describes the handling of medicines for prescribing, dispensing, supply, record keeping, storage and disposal.

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.

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[3].

Implementation of these expectations also requires revision and amendment of Controlled Drug Standard Operating Procedures.

1 Prescribing

1.1 In line with other Schedule 3 controlled drugs **all** tramadol prescriptions need to comply with the controlled drug prescription writing requirements which must contain the following details and written so as to be indelible, (e.g. handwritten in ink, typed or computer-generated):

- The patient's full name, address and, where appropriate, age.
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate (if more than one strength exists)
- The dose to be taken
- The total quantity of the preparation, or the number of dose units to be supplied, **in both words and figures**
- Signed by the prescriber with their usual signature (this must be handwritten) and dated by them (the date does not have to be handwritten).
- The date can be either the date of signing OR the date the prescriber wishes the prescription to start.
- The address of the prescriber must be stated on the prescription

[2] RPS 2005: The Safe and Secure Handling of Medicines: a team approach (Royal Pharmaceutical Society)

[3] Dept.of Health 2003: A Pharmacy Service for Prisoners

1.2 Re-scheduling provides an opportunity for full clinical review of patients prescribed tramadol in line with current guidance[4,5]. Providers are asked to review these patients ideally as soon as possible to support the transition to Schedule 3 and enable reduction in the number of patients prescribed tramadol where possible.

1.3 Prescriptions for tramadol should be prescribed as acute and non-repeatable items. Providers 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[6].

1.4 For medium to long term indications 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[7,8,9] and such patients should have their tramadol supply reviewed so that short acting preparations are switched to the longer acting versions where possible. This should be supported by considering short-acting preparations as exceptional cases and handling these via usual exceptional case handling arrangements[10.] (See Box 1)

1.5 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 British National Formulary (current edition).

Alternatives to tramadol for acute pain may be more practical given the in-possession expectations for tramadol (see section 5).

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[4] RCGP Safer Prescribing in Prisons 2011
[5] Public Health England: Management of Persistent Pain in Secure Environments 2013
[6] Dept. of Health 2006 Clinical Management of Drug Dependence in the Adult Prison Setting
[7] Summary of Product characteristics: Zydol XL 400mg

[8] Karhu D, Fradette C, et al. Comparative pharmacokinetics of a once-daily tramadol extended-release tablet and an immediate-release reference product following single-dose and multiple-dose administration. J Clin Pharmacol 2010;50(5):544-53. link to abstract

[9] Keating GM. Tramadol sustained-release capsules. Drugs 2006; 66 (2): 223-30
[10] National Prescribing Centre (NPC) 2009: Supporting rational local decision-making about medicines (and treatments)

Box 1

Exceptional Cases: These are defined as:

For an individual patient, a treatment or medicine falls outside existing contracts or policy for clinical reasons. Cases should not be used to bypass usual processes or relate to operational issues only.

Providers will have arrangements in place for consideration and decision making about exceptional cases that arise concerning routine local policies such as the in-possession policy and local formulary.

National guidance exists about the handling of exceptional cases (referred to as individual funding requests- IFRs) mainly used by commissioning organisations. However the principles in this guidance can be used to support local provider exceptional case handling.

NPC 2009 Local decision making Guidance

2 Requisitioning (i.e. ordering of Schedule 3 CD stock) and stock supply

2.1 Ordering of stock supplies of tramadol have to be via a legally signed CD requisition as detailed in the Misuse of Drugs regulations and related guidance[11]. In secure environments this means that the requisition needs to be signed by a Doctor or Pharmacist.

2.2 Signed requisitions from NHS commissioned services do not need to be on the FP10 CDF requisition form or returned to the NHS BSA Prescription Pricing Division. Suppliers including community pharmacies must retain the requisition for 2 years..

2.3 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.

2.4 Pharmacy service providers supplying stock of CDs should already have a licence that includes Schedule 3 CDs if they are supplying the secure environment with stock supplies of buprenorphine.

[11] NPC 2009: A Guide to Good Practice in the Management of Controlled Drugs in Primary Care

3 Dispensing of tramadol prescriptions by pharmacy service providers

3.1 From 10 June 2014 pharmacy service providers expect prescriptions for tramadol to meet regulatory requirements for prescription writing as detailed in section 1.1 above. Any prescription not meeting these requirements is likely to be returned for adjustment prior to supply and may cause delays in treatment.

3.2 Pharmacies will only dispense from the original hand-signed CD prescription. Healthcare providers should therefore copy and/or scan this original and retain a local copy for reference and continuity of care (see section 8).

3.3 As prisons and some IRCs are NHS commissioned services prescriptions written in these NHS services are NHS prescriptions and thus do not need to be written on a Private CD prescription form (FP10 (PCD))[10]

4 Storage and transport of tramadol in H&J sites: Stock and dispensed named patient supplies

The group decided that the security of storage of stock supplies of tramadol should be handled differently to named patient supplies. This is to

- minimise the risk of medication errors and overcrowding of stored tramadol that would exist 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:

4.1 Labelled Named Patient supplies: 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[3] **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 6 for audit/reconciliation recommendations)

4.2 Stock supplies (including over-labelled stock used to supply urgent prescriptions): There are certain circumstances where stock

tramadol needs to be supplied (for example for supply of initial doses, transferred prisoners who arrive without their own supply or for out of hours/urgent doses).

Tramadol stock needs to be kept in the CD cupboard and receipt and supply recorded as for buprenorphine (see Section 6).

4.3 Transport of tramadol: It is expected that on delivery, supplying pharmacies and wholesalers would separate out any tramadol supplied either from requisitions or dispensed tramadol.

When transported within a secure environment local arrangements should be in place to minimise security risks as detailed in PSI IDTS 2010/45[1].

5 Administration and supply:

5.1 As for other Schedule 3 CDs, all tramadol must be supplied not in possession under supervised consumption using a process that provides the same level of security and diversion minimisation as those used to administer IDTS medicines[1] and expected as per PSO 3550[12].

5.2 Recent information suggests that Category D prisons allow in-possession of tramadol. Category D prisons and other secure residential settings where tramadol is allowed in-possession need to review and amend their operational arrangements to meet the expectations within this guidance.

5.3 Exceptional cases to this policy should be handled via formal local arrangements as for other types of exceptionality[10]. Where instances of in-possession tramadol are allowed, it is recommended that adherence checks are undertaken to identify potential diversion and inform clinical reviews.

5.4 Secure environments 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.

5.5 It is expected that all secure environments supply tramadol not-in-possession and thus every secure residential setting should be

[12] Prison Service Order: PSO3550 Clinical Services for Substance misusers

able to continue to accept admission or transfer of patients prescribed tramadol.

5.6 Patient Group Directions (PGD) 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[11].

6 Recording of tramadol transactions

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

6.2 Stock supplies (including over-labelled stock used to supply urgent prescriptions): 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 IDTS PSI 2010/45[1].

7 Prescription retention

7.1 Dispensed prescriptions must be retained by the dispensing pharmacy for 2 years. Community pharmacies should not send these prescriptions to the PPD as they are not private prescriptions.

7.2 Original hand-signed prescriptions where stock tramadol is used to supply patients must be retained by the healthcare provider for 2 years.

7.3 Where secure environments 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.

8 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 briefing provides an opportunity to remind healthcare providers in all residential secure environments about the expectations of transferring patients taking Schedule 2 and 3 CDs.

8.1 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 medication on transfer as expected for all other named CD medication.

8.2 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 prison. In addition to the medication the following information is also be needed <u>on transfer</u> (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 SystmOne).

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

8.3 When patients are released from residential secure environments the requirements for supplying medication on release is unchanged. Patients prescribed tramadol need to be able to access continued doses of tramadol either by giving the patient their named supply (usually at least 7 days)[14] on release or providing a FP10 prescription (meeting the requirements detailed in section 1.1) where the release is unplanned[13] and the named supply cannot be accessed prior to release.

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[13] Dept of Health 2008: Provision of FP10 and FP10[MDA] prescription forms by HM Prison Service for released prisoners

8.4 To support transfer of care between secure environments and hospital care local healthcare providers are advised to make local agreements with secondary and tertiary care providers in line with national transfer of care guidance[14] to:

- Share information in formularies for the management of pain (acute and chronic) to enable the secure environment 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 secure environment clinician to reduce the prescribing of tramadol as soon as possible post-discharge.

9 Disposal of tramadol stock

Tramadol is exempt from Safe Custody requirements. However **in secure environments**, 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 sites:

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 providers should use CD denaturing kits in order to denature CDs **including tramadol**. These can be obtained from pharmacy service providers or waste contractors.

9.1 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.

[14] RPS June 2012: Keeping patients safe when they transfer between care providers – getting the medicines right

9.2 Stock supplies (including over-labelled stock used to supply urgent prescriptions): Stock awaiting destruction should be separated from current stock but not signed out of the CD stock record.

Tramadol stock that is expired should be destroyed in the presence of an authorised witness. Providers need to contact their Controlled Drugs Accountable Officer (within their organisation or the CDAO in the local NHS England Area Team).

9.3 Tramadol awaiting destruction should be checked as part of routine CD stock reconciliation to ensure that it is still accounted for.

10 Related issues

10.1 Mandatory Drug Testing in prisons: Once tramadol is rescheduled NOMS will trial including it in routine mandatory drug testing[15], with a view to permanent inclusion. As with all MDT failures, custody staff will 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 medication).

10.2 Patient safety incidents and prison intelligence reports (IR) involving tramadol: Any incident involving tramadol that is identified via IR or a healthcare identified patient safety incident should be formally reported using local arrangements and the national learning and reporting system. In addition these reports should be included in the submission of incidents to the organisational CD Accountable Officer (CDAO) and Area Team CDAO.

11 Implementation Tools

HMP Wakefield has completed clinical reviews and a transition to long-acting tramadol preparations which are no longer held in-possession. A summary of this programme and implementation tools are available *here*. We would like to thank the healthcare team at Spectrum Community Health for sharing this work.

[15] HM Prison Service PSO 3601 – Mandatory Drug Testing (2007)

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