

MEMORANDUM

To: NHSGGC GP practices, community pharmacies

From: Controlled Drugs Governance Team

Date: 4th June 2014

Subject: Controlled Drug status changes for ketamine, lisdexamfetamine, temazepam, tramadol, zaleplon and zopiclone 10th June 2014

Following consultation, the Home Office has announced changes in the legal classification of the above medicines which come into effect on 10 June 2014. The most notable changes affect tramadol. It has not been classed as a controlled drug to this point, but will become a Schedule 3 CD. Full details of all changes are on page 3.

Drugs can be further classified based on the risk of potential harm to the patient with Class A deemed the most dangerous and Classes B and C considered less harmful.

CONTROLLED DRUG SCHEDULE 2 or 3 PRESCRIPTION REQUIREMENTS

- Prescriptions must contain the following:
 - Prescriber's signature
 - Patient's name, address and CHI number
 - name, form and strength of drug,
 - total quantity to be supplied in words and figures,
 - dose stated in full
 - instalment amount and interval of supply to be stated if required, eg supply 4 capsules daily, supply 8 capsules on Saturday.
 - prescriptions are only valid for **28 days**
 - it is good practice to include no more than 30 days' supply on prescription
- Controlled drugs are not permitted on serial prescription.
- Private prescriptions for tramadol, like all schedule 2 and 3 CDs must be on the official Private Prescription for CD (PPCD) prescription form. Prescribers need to apply to their local Health Board for registration as a private prescriber of CDs. Contact Kate McGloan (kate.mcgloan@ggc.scot.nhs.uk) for specific details.
- Pharmacists presented with a prescription which has a minor typographical error or has the quantity present only in figures, but not words, can amend the prescription to add the missing information. Pharmacists cannot correct other errors or omissions, eg add a missing dose.

CONTROLLED DRUG SCHEDULE 2 or 3 REQUISITION REQUIREMENTS

- Requisitions must contain the following:
 - Recipient's name, address, profession and signature
 - The total quantity of drug required
 - The purpose of the requisition, eg for stock
- Private requisitions for tramadol, like all schedule 2 and 3 CDs should be on the official CDRF requisition form. Supplies can be made on other forms if all legal requirements are met.
- The Royal Pharmaceutical Society has issued guidance and frequently asked questions for members: <http://rpharms.co.uk/EQ-2HKM5-114ABE1IE4/cr.aspx>.
- CDAO Network Tramadol Frequently Asked Questions: <http://www.knowledge.scot.nhs.uk/accountableofficers/resources-library/resource-detail.aspx?id=4048217>

Summary of handling requirements for selected CDs from 10th June 2014

Drug	Store in CD cabinet?	CD Register entries required?	Prescription writing requirements	CD Requisition Requirements?
Alfentanil	YES	YES	YES	YES
Buprenorphine (including Suboxone)	YES	NO	YES	YES
Chlordiazepoxide	NO	NO	NO	NO
Co-codamol	NO	NO	NO	NO
Codeine (except injection)	NO	NO	NO	NO
Codeine injection 60mg/ml	YES	YES	YES	YES
Dexamfetamine	YES	YES	YES	YES
Diamorphine	YES	YES	YES	YES
Diazepam	NO	NO	NO	NO
Dihydrocodeine (except injection)	NO	NO	NO	NO
Dihydrocodeine injection 50mg/ml	YES	YES	YES	YES
Fentanyl	YES	YES	YES	YES
Hydromorphone	YES	YES	YES	YES
Ketamine	NO	NO	NO	NO
Lisdexamfetamine	YES⁽¹⁾	YES⁽¹⁾	YES⁽¹⁾	YES⁽¹⁾
Lorazepam	NO	NO	NO	NO
Lormetazepam	NO	NO	NO	NO
Methadone	YES	YES	YES	YES
Methylphenidate	YES	YES	YES	YES
Midazolam	NO	NO	YES	YES
Morphine (except 10mg/5ml oral solution)	YES	YES	YES	YES
Morphine 10mg/5ml oral solution	NO	NO	NO	NO
Nitrazepam	NO	NO	NO	NO
Oxazepam	NO	NO	NO	NO
Oxycodone	YES	YES	YES	YES
Phenobarbital	NO	NO	YES	YES
Temazepam	YES	NO	NO⁽²⁾	YES
Tramadol	NO	NO	YES⁽¹⁾	YES⁽¹⁾
Zaleplon	NO	NO	NO	NO
Zolpidem	NO	NO	NO	NO
Zopiclone	NO	NO	NO	NO

This document refers to the legal requirements of these drugs.

(1) From 10th June 2014

(2) Current status. This will change at a future date.

For further information, please contact a member of your local prescribing team or the Controlled Drugs Governance Team on 0141 201 5348.

Detail of Changes

Tramadol: Change in legal status to Schedule 3 CD

- Tramadol has not been classed as a CD until now.
- Stock orders: Orders must conform to CD requisition requirements.
- Storage: There is no need to store in the CD cupboard.
- Recording: No requirement to be recorded in the CD register.
- Prescribing: Tramadol must now be prescribed as a Controlled Drug. Note the requirements for interval of supply, amount per supply plus daily dose to be included if prescribing by instalments. Prescriptions are only valid for 28 days. Not permitted on serial prescription.
- PGDs: tramadol will not be able to be included on any PGDs. The national PGD for community pharmacy urgent supply will be amended.
- Destruction: Tramadol, like all Schedule 2-4 CDs, should be denatured by use of a controlled drug destruction kit before disposal in pharmaceutical waste.

Lisdexamfetamine: classification as schedule 2 CD

- Although not classed a Schedule 2 CD until 9th June, previous advice was to treat this like a Schedule 2 CD, so there should be no change to existing practice.
- Stock Ordering: Orders must conform to CD requisition requirements.
- Storage: Lisdexamfetamine should continue to be stored in the CD cupboard.
- Recording: Receipt, administration and destruction of stock must be recorded in the CD register.
- Prescribing: There are specific requirements for writing prescriptions for CDs as above. Not permitted on serial prescription.

Zopiclone and Zaleplon: classification as Schedule 4 CDs

- These drugs have not been classed as CDs until now.
- As Class C Schedule 4 CDs there are no specific requirements on ordering, storage, recording or prescription writing. The changes provide a framework within which criminal penalties are set with reference to the harm a drug has or is capable of having when misused and the type of illegal activity undertaken in regard to that drug.
- Prescriptions for all Schedule 4 CDs are only valid for 28 days.
- Not permitted on serial prescription.

Temazepam: removal of exemption from prescription writing requirements

- Remains a Schedule 3 CD subject to safe custody requirements.
- No change needed now. The Home Office plan to remove the exemption from Schedule 2 and 3 CD prescription writing requirements, but an implementation date has yet to be set.
- Once the exemption is removed any prescription must conform to the full requirements for writing prescriptions for CDs. Information will be circulated when the date is announced.
- Not permitted on serial prescription.

Ketamine:

- No changes are required to current methods ordering, storage, recording or prescribing.
- Ketamine is being reclassified to Class B, based on the evidence of harms due to acute toxicity and from long term use, particularly irreversible bladder and kidney damage.
- The scheduling of ketamine is not changing at this time; however a consultation will follow on potential rescheduling to become Schedule 2 CD. If that happens, details on the required changes in handling will then be circulated.

References:

- Home Office Response to consultation: <https://www.gov.uk/government/consultations/scheduling-of-tramadol-and-exemptions-for-temazepam-prescriptions>
- The Misuse of Drugs Act 1971 (Ketamine etc.) (Amendment) Order 2014: <http://www.legislation.gov.uk/id/ukdsi/2014/9780111110904>
- Advisory Council on Misuse of Drugs advice on tramadol: <https://www.gov.uk/government/publications/acmd-advice-on-tramadol>
- Advisory Council on Misuse of Drugs advice on ketamine: <https://www.gov.uk/government/publications/ketamine-report>