

Controlled Drugs Legislation

FAQs Changes to the Misuse of Drugs Regulations in N.I. June 2014

Summary of schedule changes

Q1. Which medicines will change their controlled drug status?

- **Tramadol will become a Schedule 3 CD** (CD No Register POM/CD3)
- like midazolam
- **Lisdexamfetamine will become a Schedule 2 CD** (CD POM/CD2)
- like morphine
- **Zopiclone and Zaleplon will become Schedule 4 Part 1 CDs** (CD Benz POM/CD4)
- like zolpidem and diazepam.



Changes to
NI Regs are
effective from
26th June
2014

Q2. When do the changes become law?

The amendments to the GB Misuse of Drugs Regulations 2001 came into force on 10th June, **and the amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 come into operation on 26th June.**

Tramadol - safe custody & records

Q3. Will tramadol need to be stored in the CD cabinet?

No, there are no safe custody requirements but it should be stored securely.

Q4. Will records need to be kept in a CD register? No

Tramadol prescriptions & requisitions

Q5. What prescription writing requirements will apply*?

- Patient's name and address
- Prescriber's name and address (which must be within the UK)
- Date and signature of prescriber including indication of prescriber type eg doctor/other
- Drug name, strength, form, and total quantity in words & figures
- Dosage instructions - 'as directed' is not acceptable however 'one as directed' is allowable
- Instalment quantities if to be supplied in instalments e.g. weekly

Q6. What needs to be written on a stock requisition (NHS or private)*?

- Name, address, profession and signature of the GP
- Purpose for which the drug is supplied
- Total quantity of the drug (both words and figures are not required).

Q7. Can a prescriber issue a private prescription for tramadol on headed note paper?

No. Tramadol must be prescribed on a PCD1 form (private prescription form for Schedule 2 and 3 CDs).

Q8. Can a pharmacist dispense an EEA (European) prescription for tramadol? No

*See section on Controlled Drugs and drug dependence in the BNF for further details.

Q9. What if a prescription was issued before 26th June 2014 but presented to the pharmacy after the date?

The new legislation will apply. The general advice is to treat these prescriptions as you would other CD prescriptions which are not completed legally. Options include contacting the prescriber for a replacement prescription, or, if there is an immediate need for the medicine and there is likely to be a delay in obtaining a replacement, after exercising professional judgment, the pharmacist may decide to make a supply from the current prescription.

Pharmacists may legally amend CD prescriptions for minor typographical errors – this includes adding the total quantity in words if the prescription only specifies the total quantity in figures. In such cases provided the pharmacist is confident the prescription is legitimate and unambiguous they may amend the prescription. Otherwise it needs to be amended by the prescriber.

Q10. What if a prescription written on or after 26th June 2014 does not comply with the requirements?

See above. Dispensing GP practices will also need to ensure that relevant prescriptions are legal.

Q11. Can tramadol be issued as an emergency supply?

No, Schedule 3 CDs cannot be supplied in an emergency and cannot be faxed (except phenobarbital or phenobarbital sodium for epilepsy).

Q12. Can a prescription be issued for more than 30 days supply?

Yes, although it is not a legal requirement, it is a good practice requirement that CD prescriptions should be for a maximum of 30 days. Prescribers issuing more than a 30 day supply of tramadol should be prepared to justify and record their decision. In line with this, prescribers may wish to review current prescription quantities.

Tramadol prescription validity

Q13. How long is a tramadol prescription valid for?

28 days from the date signed, or the appropriate date if specified.



Q14. Can pharmacists dispense a balance for tramadol after 28 days?

No, all balances must be dispensed within the 28 day period.

Q15. Are prescriptions written before 26th June valid for 28 days or for 6 months?

The new legislation will apply and so these prescriptions will be valid for 28 days.

Tramadol on instalment (weekly) prescriptions

Q16. Can tramadol be prescribed on an instalment (e.g. weekly) basis?

Yes, if it is assessed that there is a clinical need for this, in line with the NI Drug Tariff. As a Schedule 3 CD with prescription writing requirements, the prescription will have to comply with instalment requirements i.e. the quantity to be supplied at each instalment must be stated as well as the interval to be observed.

Q17. Is an instalment prescription for tramadol that lasts longer than 28 days allowable?

Yes, as long as the first instalment is dispensed within the 28 day period.

Q18. Can tramadol be dispensed into a Monitored Dosage System (MDS)?

Yes, if the pharmacist considers that there is a clinical need for this.

Tramadol on repeat dispensing prescriptions

Q19 Can tramadol be issued on repeat dispensing prescriptions?

No, Schedule 3 CDs cannot be issued using repeat dispensing.

Q20. What should be done about current repeat dispensing prescriptions for tramadol?

GPs:

- Patients receiving tramadol on repeat dispensing should be identified, reviewed, and tramadol then removed from repeat dispensing. If appropriate, a replacement 'stand-alone' prescription can be issued.
- Patients should be informed of the changes and the implications for obtaining future supplies.

Community Pharmacists:

- Pharmacists should check repeat dispensing prescriptions that they currently hold for tramadol and contact the prescriber to request a review. If appropriate, a replacement 'stand-alone' prescription can be issued.
- Outstanding batch prescriptions should be endorsed 'not dispensed' prior to submission to BSO for processing.

Tramadol - other FAQs

Q21. Can a patient's representative collect tramadol for them? Yes

Q22. What needs to be recorded by the pharmacy when a tramadol prescription is collected?

The patient/representative should be asked to sign the back of the prescription form stating they have collected the CD item.

Q23. How should I destroy out of date/no longer required tramadol?

- As for all CDs, GP stocks of tramadol which are no longer required or out-of-date, should be returned to a community pharmacy for destruction.
- In line with normal practice, patients/carers should also be encouraged to return medicines that are no longer needed or which are out-of-date to the community pharmacy for destruction.
- Tramadol must be denatured before disposal however destruction does not need to be supervised by an 'authorised witness'.

Q24. Will a licence be required to import or export tramadol to/from the UK? Yes

Lisdexamfetamine

Q25. Lisdexamfetamine will become a Schedule 2 CD, what are the main changes?

It will be subject to the controls outlined for tramadol (Schedule 3), **plus**:

- Must be stored in either a locked CD safe/cabinet or doctor's bag
- All receipts and supplies must be recorded in the CD register
- Destruction must be supervised by an 'authorised witness'.

Zopiclone and Zaleplon

Q26. Zopiclone & zaleplon will join zolpidem and become Schedule 4 CDs, what are the main changes?

- Prescriptions should be for a maximum of 30 days' supply (good practice).
- Prescriptions will be valid for 28 days from the date signed, or the appropriate date if specified
- All balances must also be dispensed within this timeframe
- Supplies which are out of date or no longer required, should be returned to a community pharmacy for destruction and must be denatured before disposal.
- A licence will be required to import or export zopiclone or zaleplon to/from the UK.

Temazepam

Q27. Are there any changes to the legal requirements for temazepam?

No, temazepam is exempt from any change to its current prescription requirements but this is still under review. The exemption may be removed in the future, however the current position for temazepam remains as before.

Ketamine

Q.28 Are there any changes to the legal requirements for ketamine?

Not at present but there is consultation due on potential re-scheduling from a Schedule 4 to Schedule 2. If this happens, details on the required changes in ordering, storage, recording or prescribing will be advised.

Further information

For further details on the safe management and use of CDs in primary care, please refer to:

1. HSCB Information on controlled drugs in primary care
www.medicinesgovernance.hscni.net
2. DHSSPS 'Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)'
<http://www.dhsspsni.gov.uk/index/pas/pas-lie/pas-accountable-officer/pas-guidance.htm>
3. BNF Guidance on Prescribing - Section on Controlled drugs & drug dependence.

If you have any queries in relation to the CD legislation changes, please contact a member of the Pharmacy and Medicines Management Team in your local HSCB office.