

Controlled drug changes to the legal classifications of tramadol, lisdexamfetamine, zopiclone and zaleplon – professional guidance and frequently asked questions

We can now confirm (20th May 2014) that legislation has been approved by Parliament and that the following legislative changes will come into force on **10th June 2014**:

Tramadol will become a Schedule 3 controlled drug (CD No Register POM), but will be exempt from safe custody regulations.

Lisdexamfetamine will become a Schedule 2 controlled drug (CD POM).

Zopiclone and **zaleplon** will become Schedule 4 part 1 controlled drugs (CD Benz POM)

The table below summarises various characteristics of the affected drugs that will apply from **10th June 2014**.

	Tramadol	Lisdexamfetamine	Zopiclone	Zaleplon
Designation from 10 th June 2014	Schedule 3 (CD No Reg POM)	Schedule 2 (CD POM)	Schedule 4 (Part I) (CD Benz POM)	Schedule 4 (Part I) (CD Benz POM)
Safe custody regulations apply	No	Yes	No	No
Controlled drug 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
EEA and Swiss prescribers can legally prescribe	No	No	Yes	Yes
Prescription is repeatable (e.g. 'repeat x 3')*	No	No	Yes	Yes
Emergency supply	No	No	Yes	Yes
Controlled drug Requisition necessary	Yes	Yes	No	No
Requisition to be marked by supplier	Yes	Yes	No	No
Licence required to import or export	Yes	Yes	Yes	Yes
Denature before disposal*	Yes	Yes	Yes	Yes

*See MEP 37 section 3.7 for further information

Why have these changes been made?

The Advisory Council on the Misuse of Drugs (ACMD) was established under the Misuse of Drugs Act 1971. It is the duty of the ACMD to keep drugs misuse in the UK under review, and to advise the government on measures for preventing misuse and social problems arising from it. The ACMD have made these recommendations to the Home Office because they consider that these drugs can be harmful when misused.

Tramadol: The legislation changes are in response to a review carried out by the ACMD following an increasing number of reports within the NHS of tramadol's and harms when misused, including an increase in deaths where tramadol was mentioned in the reports.

Lisdexamfetamine: Lisdexamfetamine is a prodrug of dexamfetamine, which is already a schedule 2 controlled drug. The ACMD recommended that lisdexamfetamine is controlled in the same manner.

Zopiclone and Zaleplon: Zolpidem is already a schedule 4 controlled drug. The ACMD considers the risk of diversion and misuse, and the consequent harms to be similar for all three of the 'z-drugs' and recommends that zopiclone and zaleplon are controlled in the same manner.

These drugs have legitimate medical uses, but people should be under no illusion, taking them without prescription and medical advice can be dangerous. Where the prescribing of these medicines is clinically appropriate, the Royal Pharmaceutical Society and the Home Office intend to ensure that the new legislation should not disrupt patient care. In light of this, we have prepared professional guidance together with the Home Office to some frequently asked questions below.

What should I do if I receive a prescription written, signed and dated before 10th June 2014?

Each prescription presented in these circumstances will need to be considered on a case by case basis. The pharmacist will need to exercise his or her own professional judgement, taking into account the best interests of the patient and whether or not there is an immediate need for the medicine.

Options could 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 prescription, after exercising professional judgement, the pharmacist may decide to make a supply from the prescription that is currently in their possession.

What about prescriptions awaiting collection and owings?

Prescriptions and owings that are awaiting collection from before 10th June 2014 should be checked, assessed for clinical appropriateness (taking into account the length of time that the prescription or owing has been awaiting collection), and if necessary the prescriber should be contacted to review the prescription and issue a replacement.

What should I do if a patient presents to collect a prescription or owing written, signed and dated before 10th June 2014?

See 'What should I do if I receive a prescription written, signed and dated before 10th June 2014?' above.

Are prescriptions written before 10th June 2014 and presented after 10th June 2014 valid for 28 days or for 6 months?

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

What is the maximum quantity that I can supply against a prescription written before 10th June 2014 and presented after 10th June 2014?

The maximum quantity supplied should not exceed 30 days, in line with the Department of Health and Scottish Government recommendations for Schedule 2, 3 and 4 controlled drugs.

Does this mean that tramadol, zopiclone and zaleplon can no longer be prescribed on NHS repeat dispensing prescriptions (England and Wales)?

Schedule 2 and 3 controlled drugs cannot be prescribed as part of the NHS repeat dispensing scheme and so tramadol cannot be prescribed under these arrangements. Zopiclone and zaleplon, as Schedule 4 Part 1 drugs, can be repeat dispensed. However the first dispense must take place within 28 days.

How do I manage patients who currently have tramadol included on their NHS repeat dispensing prescriptions?

Pharmacists should check all NHS repeat dispensing prescriptions that they currently hold for tramadol, assess them for clinical appropriateness and contact the prescriber to request a review and if they decide that it is appropriate, a replacement prescription on an appropriate form (FP10 for England or WP10 for Wales).

What should I do if a patient presents to collect an NHS repeat dispensing prescription after the 10th June 2014?

See 'What should I do if I receive a prescription written, signed and dated before 10th June 2014?' above.

Does this mean that tramadol, zopiclone and zaleplon can no longer be prescribed on CMS serial prescriptions (Scotland)?

Schedule 2, 3 and 4 controlled drugs cannot be prescribed on CMS serial prescriptions.

How do I manage patients who currently have these included on their CMS serial prescriptions?

Pharmacists should check all CMS serial prescriptions that they currently hold for these medicines, assess them for clinical appropriateness and contact the prescriber to request a replacement prescription on a GP10 form.

What should I do if a patient presents to collect a CMS serial prescription after 10th June 2014?

See 'What should I do if I receive a prescription written, signed and dated before 10th June 2014?' above.

My local GP's prescribing software has not been updated and I expect to receive prescriptions issued after the 10th June that do not meet the new legal requirements – what do I do?

GP prescribing system administrators have been notified of the changes to prescription requirements and are updating their systems. The general expectation is that prescribing systems will be updated prior to 10 June. However, we are aware that some systems may not be updated in time for 10th June 2014 and may generate prescriptions that do not meet the new legal requirements.

In these circumstances, use your professional judgment on a case-by-case basis bearing in mind that the intentions of the changes are to prevent misuse and harm without disrupting clinically appropriate supplies to patients. Take into account the best interests of the patient and whether or not there is an immediate need for the medicine. Depending upon the circumstances, options could include contacting the prescriber to ask them to amend the prescription, or, if there is an immediate need for the medicine and there is likely to be a delay in obtaining an amended prescription, the pharmacist may decide to make a supply from the prescription that is currently in their possession.

It could be useful to maintain contact with the GP practice to keep a tab on when systems are expected to be updated. By the beginning of July 2014 we would expect all prescriptions to meet their full legal requirements.

I was expecting the current exemption of temazepam from schedule 2 and 3 prescription form requirements to be removed as part of this legislation – is this the case?

No, the Home Office are currently reviewing this. The exemption has not been removed as part of the legislation coming into force on 10th June 2014 and temazepam will still be exempt from schedule 2 and 3 prescription form requirements after 10th June 2014.

Further information

Details of the legislation can be found in [SI 2014/1275 The Misuse of Drugs and Misuse of Drugs \(Safe Custody\) \(Amendment\) \(England, Wales and Scotland\) Regulations 2014](#)

Royal Pharmaceutical Society Professional Judgement Quick Reference Guide:

<http://www.rpharms.com/support-resources-a-z/professional-judgement-quick-reference-guide.asp>

Members requiring further information on this topic, please contact the RPS Support Team on 0845 257 2570 or email support@rpharms.com.

Pharmacists working in hospital and primary care settings may also wish to discuss the legislation changes with their Accountable Officer to ensure that they take into account any local policies or procedures that may be in place.