

February 2019

PSNC Briefing 010/19: Reclassification of gabapentin and pregabalin as CDs

From 1st April 2019, [amendments](#) to the Misuse of Drugs Regulations 2001 and the Safe Custody Regulations 1973 come into force which mean that pregabalin and gabapentin will be reclassified as Schedule 3 Controlled Drugs (CDs).

Introduction

The reclassification follows Government consultation and recommendations from the Advisory Council on the Misuse of Drugs for additional safeguards to be put in place because of concerns around the misuse of these drugs. However, pregabalin and gabapentin will be included in the list of “exempted drugs” in the safe custody regulations which means that community pharmacy teams will not be required to keep these drugs in the CDs cabinet.

Requirements for gabapentin and pregabalin from 1st April 2019 are as follows:

Controlled Drug	Prescription requirements	Prescription validity	Safe custody requirements	Entry in CD register	Emergency supplies	Repeat dispensing
Gabapentin	✓	28 days	✗	✗	✗	✗
Pregabalin	✓	28 days	✗	✗	✗	✗

Prescription requirements

From 1st April 2019, all gabapentin and pregabalin prescriptions will be subject to the following [prescription writing requirements for Schedule 3 CDs](#):

- Patient name and address
- Prescriber’s address
- Prescriber’s signature
- Date of prescriber’s signature
- Drug name, strength and formulation
- Dose (Note: ‘as directed’ is NOT acceptable; ‘one as directed’ is acceptable)
- Total quantity (in both words and figures)

Validity of prescriptions

Prescriptions for [Schedule 3 CDs](#) are valid for 28 days after the appropriate date on the prescription. The appropriate date is either the signature date or any other date indicated on the prescription (by the prescriber) as a date before which the drug should not be supplied – whichever is the later. Learn more on our [prescription validity periods webpage](#).

Repeat dispensing

Following the change, it will be illegal to supply pregabalin and gabapentin through repeat dispensing, i.e. paper FP10 RD forms or electronic repeat dispensing (eRD). This means prescribers must not issue repeatable prescriptions for these drugs.

Prescribing via EPS

Some GP practices are [piloting EPS CDs](#) so you may receive and dispense a mix of EPS/paper prescriptions for gabapentin and pregabalin before and after the schedule changes occur on 1st April.

Emergency supplies

Schedule 3 CDs cannot be supplied in an emergency without a valid prescription, except for phenobarbitone or phenobarbitone sodium for epilepsy.

Storage and record-keeping requirements

Pregabalin and gabapentin will be included in the list of “exempted drugs” in the safe custody regulations which means that they will not be required to be kept in the CD cabinet. This follows representations from PSNC and others that the usual storage arrangements for Schedule 3 CDs would not be practical for pharmacies to comply with considering the significant number of prescriptions for these drugs (see [PSNC’s response to the original Home Office consultation](#) for full details).

Schedule 3 CDs are also exempt from record-keeping requirements.

Changes to prescribing systems

Updates will have to be made to general practice clinical systems ahead of 1st April 2019 to support the reclassification of gabapentin and pregabalin as CDs. The timing of this will depend on system suppliers, but updates will need to be completed by 31st March 2019.

NHS England has informed PSNC that EMIS has implemented updates to its general practice clinical system to be in place by 15th February 2019. This means paper prescriptions will automatically replace any prescriptions previously sent by EPS. If a patient’s other prescription items are issued via EPS, there is a risk that the paper script for pregabalin or gabapentin may not be collected from the GP practice; pharmacy teams should be alert to this risk and should advise patients that the paper script will need to be collected from the practice (or the pharmacy could offer to collect the script for the patient if you provide a prescription collection service).

Advice for pharmacy teams

Prescriptions and owings awaiting collection from before 1st April 2019 should be checked, assessed for clinical appropriateness (taking into account the length of time that the prescription or owing has been awaiting collection), and where necessary, the prescriber should be contacted for a replacement prescription.

Community pharmacy teams should also check all NHS repeat dispensing prescriptions that they currently hold for gabapentin and pregabalin, ensuring that all batch issues dispensed prior to the 1st April are claimed for no later than the 5th April. Any remaining issues from the batch which have not been dispensed should be returned to the prescriber/spine and a replacement prescription requested as repeat dispensing prescriptions will not be valid after 1st April 2019.

For more information, please visit the [Government website](#) and the [UK legislation website](#).

Frequently Asked Questions

Q. When gabapentin and pregabalin become Schedule 3 CDs, will they need to be stored in the CD cabinet?

A. No, because gabapentin and pregabalin will be exempt from the safe custody requirements.

Q. Will records need to be kept in a CD register of purchase and supply of these drugs?

A. No, because entries in a CD register are only required for Schedule 1 and 2 CDs.

Q. A patient has presented a gabapentin prescription in April 2019, but it was issued before 1st April – how long is it valid for?

A. The new legislation will apply to prescriptions dispensed after 1st April 2019, so these prescriptions will only technically be valid for 28 days from the appropriate date.

Q. Does this mean that gabapentin and pregabalin can no longer be prescribed on NHS repeat dispensing prescriptions?

A. Schedule 2 and 3 CDs cannot be prescribed as part of the NHS repeat dispensing scheme. As of 1st April 2019, this means gabapentin and pregabalin will not be eligible for repeatable prescriptions.

Q. Will pharmacies be remunerated for the Schedule 3 CD fee if prescriptions for gabapentin and pregabalin are issued before 1st April 2019 that comply with the CD regulations?

A. The NHS Business Services Authority (NHSBSA) has advised PSNC that, irrespective of the date of issue, payment would relate to the month in which a prescription is submitted for payment. For example, if a pregabalin or gabapentin prescription is submitted with the bundle prepared in early April (for the March dispensing month) then a Schedule 3 CD fee would not be paid to the contractor, but if the prescription is submitted for payment with the bundle prepared in May (for the April dispensing month) then a Schedule 3 CD fee would be paid. Please note, Clause 5A of the Drug Tariff stipulates that forms should be dispatched to the NHSBSA not later than the 5th day of the month following the month in which the supply was made.

Q. Will exemption for emergency supply to people with epilepsy (as with phenobarbital) be in place?

A. No. Community pharmacy teams will not be permitted to provide emergency supplies of pregabalin or gabapentin. Whilst an exception has been made for phenobarbital, no such exception exists for pregabalin or gabapentin.

Q. Can I dispense a gabapentin and pregabalin prescription for more than 30 days' supply?

A. The recommended maximum limit of 30 days' treatment of a Schedule 2, 3 or 4 CD is good practice rather than a legal requirement.

Q. Can I dispense a prescription for 'pregabalin 20mg/ml oral solution sugar free' requesting less than 30 days' supply but where the product is a special container only available in a pack size that exceeds 30 days' supply?

A. Where the quantity ordered by the prescriber does not coincide with that of an original pack (or sub-pack when the special container status is placed on the sub-pack) and the product is considered a special container, contractors are required to supply the special container or combination of containers nearest to the quantity ordered and endorse the prescription form with the number and size of these containers. Should a prescription be issued for 'pregabalin 20mg/ml oral solution sugar free' the pharmacy would still be reimbursed for the full pack size as per existing special container rules even though more than the prescribed amount was dispensed even if this exceeded the recommended 30 days' supply.

Q. Can gabapentin and pregabalin be supplied in a compliance aid?

A. There are no restrictions in placing CDs into compliance aids; however, the pharmacist needs to be satisfied that the drugs will remain stable when placed outside its original container.

If you have queries on this PSNC Briefing or you require more information, please contact [PSNC's Dispensing and Supply Team](mailto:info@psnc.org.uk).