

Rescheduling of Gabapentin and Pregabalin as Schedule 3 Controlled Drugs

Guidance: *For urgent action*

From 00:00 on 1 April 2019, gabapentin and pregabalin will be [reclassified as Schedule 3 controlled drugs](#) under the Misuse of Drugs Regulations 2001, and Class C of the Misuse of Drugs Act 1971. They will be exempted from the safe custody requirements under the Misuse of Drugs (Safe Custody) Regulations 1973.

It is not helpful or appropriate for anyone to stockpile these medicines

Prescribers:

1. In addition to the normal prescription requirements for prescription only medicines (as required by the Human Medicines Regulations 2012), prescriptions for Schedule 3 controlled drugs must also contain (as outlined in the Misuse of Drugs Regulations 2001):
 - Dose (which must be clearly defined; 'as directed' is not acceptable)
 - Date on which it was signed
 - Address of the prescriber
 - Formulation
 - Strength (where appropriate)
 - Total quantity or dosage units of the preparation in both words and figures
 - An appropriate date: prescriptions 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.
2. The Department of Health and Social Care has issued strong recommendations that the maximum quantity of Schedule 3 drugs prescribed should not exceed 30 days.
3. Prescribers must not issue repeatable prescriptions. This is distinct from issuing a repeat prescription, which can continue to be issued on a monthly basis by the practice, with either an electronic signature or wet signature attached.

4. Controlled drug register entries are not required.

Emergency supply:

5. Emergency supply, including under the [NHS Urgent Medicines Supply Advanced Service](#) (NUMSAS), is not permitted. There must be a valid controlled drug prescription to obtain supplies from a pharmacy. NUMSAS referrals may still be made by NHS 111 and so the pharmacist will need to assess clinical need as usual. If necessary, the pharmacist should contact the local GP out of hours services to refer the patient.

Dispensers:

6. From 1 April 2019, it will be illegal to supply pregabalin and gabapentin through repeat dispensing, e.g. paper FP10 RD form or electronic repeat dispensing (eRD). Even if the prescription has a date which is prior to April 2019.
7. Prescriptions containing gabapentin and pregabalin can be legally dispensed if they comply with controlled drug prescribing and supplying regulations. Any prescriptions without the valid details will be illegal and the patient will need to ask the prescriber for a new prescription.
8. Any items outstanding from prescriptions issued before 1 April 2019 cannot be issued to the patient and will need to be returned to stock and prescriptions annotated accordingly when sent to the NHS BSA for payment. Patients should be advised of this situation before an incomplete prescription with an owing is dispensed.
9. Prescriptions are valid for 28 days after the appropriate date (as outlined in paragraph 1 above) on the prescription. This includes any supply owed to the patient due to insufficient stock levels in the pharmacy.
10. Patients or their representatives will need to sign and show proof of identity when they collect their medicines.

Electronic Prescription Service (EPS):

11. Suppliers of EPS systems will update their systems to support the change. The timing of this will depend on system suppliers and NHS Digital will publish this [information on its website](#) at it becomes available.

12. Once the update is rolled out, unless the GP practice is using EPS controlled drugs functionality, systems will stop adding pregabalin and gabapentin to EPS, and will automatically print a paper prescription.
13. Although system suppliers will make these changes prior to 1 April 2019, gabapentin and pregabalin prescriptions should not be treated as Schedule 3 controlled drugs until 1 April 2019. Pharmacies will not be remunerated the Schedule 3 controlled drug fee for prescriptions issued before 1 April 2019 even if the prescription is written in a way that complies with the regulations.
14. Practices which are already using the EPS Schedule 2 and 3 Controlled Drugs functionality by 31 March 2019 can continue to use EPS for controlled drugs.
15. Existing prescriptions on the spine will not be pushed back to clinical systems. GPs and pharmacists will need to deal appropriately with these.

Other:

16. The destruction of patient returns and out of date and obsolete stock will need to be carried out in line with Schedule 3 controlled drugs regulations.

Recommended actions:

For GP practices:

- Ensure your practice team is aware of the change.
- Check the NHS Digital website or contact your system supplier to find out the date of the update to the EPS system.
- When your update has occurred, check that paper prescriptions are being printed correctly with the quantity in words and figures and dose defined (see Paragraph 1).
- Identify all repeatable prescriptions for pregabalin and gabapentin, stop repeat dispensing and put transition arrangements in place for patients as early as possible before 1 April 2019.
- Inform all patients currently taking pregabalin and gabapentin about the impact this change will have on their prescriptions. Ask them to ensure they request any prescriptions in plenty of time, to help the NHS to manage the transition process. Invite them to have a 'shared decision-making'

conversation with their GP or clinical pharmacist if they would like to discuss any issues with their medicine.

- From 1 April 2019, report any incidents, concerns or stock discrepancies to the NHS England local controlled drug accountable officer in line with all other Schedule 3 medicines.

For pharmacies:

- Ensure your pharmacy team is aware of the change in the law and understands the new process with regard to prescriptions for pregabalin and gabapentin as outlined in this guidance.
- Communicate about this change to patients and answer any questions they may have. Encourage them to speak to their GP practice if in doubt about their next prescription.
- Avoid 'owing' any supply to the patient over the rescheduling period.
- If your pharmacy is set up to deliver NUMSAS, ensure staff are aware that pregabalin and gabapentin cannot be supplied via this process from the 1 April 2019. As with other controlled drugs, referrals from NHS 111 may still be made and the pharmacist's role will be to clinically assess the patient and offer appropriate clinical advice.
- From 1 April 2019, report any incidents, concerns or stock discrepancies to the NHS England local controlled drug accountable officer in line with all other Schedule 3 medicines.

Further information:

Please speak to your NHS England local pharmacy contracts manager or controlled drug accountable officer.

[Patient leaflet](#) – please hand to patients during March 2019.