

Publications Gateway Reference 03188

Pregabalin – Frequently Asked Questions

Warner-Lambert Company LLC is engaged in a dispute with a number of generic pharmaceutical suppliers regarding pregabalin, which remains on patent for one indication, namely, the treatment of pain. As part of that dispute, the Court has required NHS England to issue the guidance, which CCGs should distribute to all GP practices which are members of their CCG, and which the NHS Business Services Authority should distribute to all community pharmacies, on or before Friday 6th March 2015.

NHS England has compiled this list of frequently asked questions and responses to assist the understanding and implementation of the Pregabalin Guidance.

1. Why has NHS England issued this guidance?

The guidance has been issued because Warner-Lambert has a patent covering pregabalin for the treatment of pain, but generic suppliers are free to supply their versions of pregabalin for any other indication. To help clear up any confusion, the Patents Court ordered NHS England to distribute the guidance. Warner Lambert, NHS England and all the interested generic suppliers were either in court or aware of the hearing and were able to comment on the guidance.

2. Does this guidance only apply to brand new prescriptions for pregabalin for the treatment of neuropathic pain or does it include repeat prescriptions?

The guidance applies to all prescriptions of pregabalin for neuropathic pain. For brand new prescriptions, we ask you to implement the guidance immediately. For repeat prescriptions, you should implement the guidance when reasonably possible. Some surgeries may choose to update prescriptions in one go, for others you may choose to update the prescription at the time of issuing a repeat prescription or on review with the patient.

3. When does Warner Lambert's patent for the use of pregabalin for treating pain expire?

The patent expires on 16 June 2017. NHS England will issue further guidance when the patent expires, or if it is revoked before then.

4. When prescribing for neuropathic pain, what may be written on the prescription?

If you are prescribing pregabalin for neuropathic pain, please prescribe using the brand name Lyrica. If you are not prescribing pregabalin, please prescribe in accordance with normal practice.

5. When prescribing pregabalin for non-neuropathic pain, what may be written on the prescription?

Lyrica is licensed for the treatment of neuropathic pain, epilepsy and General Anxiety Disorder. Prescribing Lyrica for the treatment of non-neuropathic pain is off-label prescribing and is a matter for the GP and the patient and is not the subject of specific guidance from NHS England. However, we note that Warner-Lambert's patent covers pregabalin for the treatment of pain (in general).

6. When prescribing pregabalin for anything other than pain what may be written on the prescription?

If you are prescribing pregabalin for anything other than the treatment of pain, the guidance suggests prescribing using the generic name pregabalin, although you should continue to exercise your clinical judgment and are free to prescribe by reference to a specific brand where appropriate.

7. Will the practice receive extra money to implement these changes?

There are no additional funds to cover costs of implementing this action, however by implementing the changes when reasonably possible surgeries should be able to reduce the impact of these changes.

8. Where a prescription for generic pregabalin is for a condition other than the treatment of pain, what should a pharmacist do?

Pharmacists should dispense in accordance with their normal practice.

9. Where a prescription for a branded form of pregabalin (but not Lyrica) mentions or the pharmacist has been told it is for the treatment of pain, what should a pharmacist do?

We suggest the pharmacist takes this up with the prescribing doctor. The PSNC has produced a helpful template letter for pharmacists. <http://psnc.org.uk/our-news/dispensing-of-lyrica-pregabalin/>.

10. Where a prescription for a branded form of pregabalin (Lyrica or any other brand) does not mention the condition being treated, what should a pharmacist do?

The pharmacist should dispense in accordance with the prescription and normal practice.

11. What should I do if I have any other questions?

The PSNC has published further helpful FAQs here: <http://psnc.org.uk/our-news/dispensing-of-lyrica-pregabalin/>. Otherwise, please contact your local CCG.

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