

To:

Health and justice commissioners and providers
 Public Health England health and justice leads
 Her Majesty's Prison and Probation Service
 Home Office immigration removal centre leads
 Health and justice clinical networks
 CQC health and justice and controlled drug leads
 NHS England controlled drug accountable officers

Health & Justice, Armed Forces and Sexual Assault Referral Centres (SARCs)
 NHS England
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Gateway **000060**

Dear colleagues

Re: Handling of gabapentin and pregabalin as Schedule 3 Controlled Drugs in health and justice commissioned services

The purpose of this letter is to inform NHS England commissioned health and justice services and key stakeholders about the expectations for the handling of gabapentin and pregabalin as Schedule (Sch) 3 Controlled Drugs (CDs) from 1 April 2019.

Background

In January 2016, the Advisory Committee for the Misuse of Drugs recommended that pregabalin and gabapentin are scheduled as Sch 3 CDs within the Misuse of Drugs Act 1971 and associated regulations¹.

The rationale for this advice was due to:

- an increased record of deaths where these medicines were included on death certificates as a cause
- evidence of misuse is well documented and rising
- medical harms:
 - pregabalin and gabapentin related mortalities
 - physical dependencies
 - the propensity to cause depression of the central nervous system, resulting in drowsiness, sedation, and respiratory depression
- social harms: criminal behaviour associated with illicit use of these medicines.

In September 2018, the Home Office announced the outcomes of their consultation

¹ January 2016: ACMD advice on pregabalin and gabapentin ([link](#))

and the changes to the regulations that will apply from 1 April 2019²:

Pregabalin and gabapentin will become Sch 3 CDs without Safe Custody from 1 April 2019.

As was the case for the rescheduling of tramadol in 2014, policy decisions are needed to describe the regulatory requirements and expectations for the handling of these medicines by health and justice providers.

The remainder of this letter describes how these medicines should be handled within health and justice commissioned services. These expectations have been ratified by the NHS England Health and Justice Clinical Reference Group, chaired by Dr Linda Harris.

What health and justice providers must do to meet the regulatory changes

All healthcare providers and practitioners must comply with the amended regulations from 1 April 2019. The scheduling of gabapentin and pregabalin as Sch 3 CDs (excluding Safe Custody) will require the same mandatory requirements as tramadol, which were issued in 2014 by NHS England. These are available [here](#) and can be used to inform health and justice providers about the changes to the regulations³.

In summary these require changes in practice for:

- CD prescription requirements with validity of the prescription being limited to 28 days and 'wet signing' of the prescription
- Requisitioning of stock with the requisition being signed by a doctor or pharmacist
- Denaturing of the CD before disposal.

Additional expectations health and justice providers must meet to maximise the safe handling of these medicines in all health and justice secure environments

As for other Sch 3 CDs, additional operational changes for the handling of pregabalin and gabapentin are needed in health and justice settings, which align with health and justice standards and best practice. As the scheduling of these medicines is the same as tramadol, the health and justice policy for tramadol handling has been used as the basis for the handling of pregabalin and gabapentin in health and justice settings.

This requires the following CD handling practices **from 1 April 2019:**

- People prescribed these medicines should be formally reviewed in order to ensure prescribing is clinically indicated and in line with national clinical guidance (including the NHS England prison pain management formulary and related guidance).

² Home Office October 2018: Government response to the consultation for the rescheduling of gabapentin and pregabalin ([link](#))

³ NHS England 2014 Guidance for the Handling of Tramadol in Health and Justice Residential Sites [link](#)

- These medicines should continue to be supplied as named patient supplies with stock reserved for urgent / interim supplies.
- Sites are advised to store stock pregabalin and gabapentin in the CD cupboard, but named patient supplies can be stored with the person's other medication.
- Security of transport of CD stock in health and justice sites should apply to these medicines.
- Records and witnessing of the supply of pregabalin and gabapentin should be handled as follows:
 - Labelled named patient supplies: Doses administered must be recorded on the electronic administration system as for other medications. Local CD standard operating procedures need to provide assurance (via audit or reconciliation of the patient labelled medication) that patient labelled supplies of these medicines are not subject to unexplained loss or gain.
 - Stock supplies (including over-labelled stock used to supply urgent prescriptions): Recording of stock of pregabalin and gabapentin within healthcare, wings (and other treatment rooms) and on-site pharmacies should be made in a CD record book with documentation of the elements required for a Sch 2 CD register. This brings the handling of this stock in line with the requirements for buprenorphine in IDTS PSI 2010/45 and tramadol.
- As with other CDs (except for methadone and buprenorphine), supplies on transfer between sites and on release will be needed in line with national standards. This ensures continuity of care.

In-possession (IP) policy expectations, associated challenges and action taken to address them

- In all health and justice sites, **except for Category D open prisons**, pregabalin and gabapentin **must be supplied not in possession under supervised consumption** using a process that provides the same level of security and diversion minimisation as those used to administer other Sch 3 CDs.
- The implementation of not in-possession in **Category D open prisons** has specific challenges. These have been considered when agreeing the gabapentin and pregabalin handling policy for these sites and are shown in the box on the following page.

Challenges for not in-possession medicines supply in Category D prisons:

- There is no provision of seven day healthcare services in most Category D prisons.
- The need for twice daily dosing as a minimum for these medicines means that arrangements in place for tramadol (which is once daily) would not be possible for pregabalin and gabapentin.
- As prisoners are often working outside the prison or released on temporary licence as part of their rehabilitation, this creates additional issues for ensuring supplies of medicines can be accessed continually.
- The principle of rehabilitation of prisoners in open prisons is to support them in managing their lives post-release. Restriction of these medicines to supervised consumption goes against this principle of increased responsibility for their daily routine.
- Prisoners are sometimes prevented from moving to an open site because they are prescribed a Sch 3 CD which is justified for legitimate clinical reasons. This affects their overall rehabilitation pathway.

To address these concerns, collaboration with stakeholders from the open prisons was undertaken. The expectation for the in-possession policies for gabapentin and pregabalin was agreed and ratified as follows:

- **Category D prisons can supply gabapentin and pregabalin up to seven days IP with additional safeguards to reduce the risk of harm from diversion and abuse.**
- A variety of safeguards were discussed, but further work is needed to explore the benefits and risks of each and to agree whether providers can select from a 'menu of choices' or whether one or more of the safeguards should be mandated. Consideration will be given to reviewing the current policy for tramadol for Category D open prisons as part of this process.
- **Until the formal safeguards have been agreed, Category D healthcare providers and Her Majesty's Prison and Probation Service colleagues should identify ways to minimise the risk of abuse and diversion of in-possession gabapentin and pregabalin.**

Action needed by health and justice commissioners

Regional and local health and justice commissioners should use their contract or service quality monitoring arrangements to confirm that the expectations described in this letter will be implemented within their commissioned services from 1 April 2019.

The regulations must be met by all health and justice providers from this date.

It is acknowledged that in order to meet the regulatory and additional expectations, health and justice providers may require additional resources. Health and justice commissioners are encouraged to support applications from providers for these resources using local governance arrangements.

In the event that a provider is unable to meet the additional expectations by 1 April 2019, commissioners are advised to request from the provider:

- A detailed impact assessment that describes the changes needed to meet the additional expectations and why these cannot be met from 1 April 2019.
- An action plan that describes the steps that will be taken to progress implementation with dates of completion for each step.

Thank you for your support with this important legislative change.

Should you have any questions about the contents of this letter, please email Denise Farmer, Pharmaceutical Adviser Health and Justice, NHS England at denisefarmer@nhs.net.

Yours faithfully,



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Centres (SARCs)
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