Submission to the Home Office in response to their consultation on the scheduling of tramadol, and a review of exemptions for temazepam prescriptions, under the Misuse of Drugs Regulations 2001

by HM Inspectorate of Prisons

Introduction

1. We welcome the opportunity to submit information to the Home Office in response to the consultation on the scheduling of tramadol, and a review of exemptions for temazepam prescriptions, under the Misuse of Drugs Regulation 2001.

2. Her Majesty's Inspectorate of Prisons (HMI Prisons) is an independent inspectorate whose duties are primarily set out in section 5A of the Prison Act 1952. HMI Prisons has a statutory duty to report on conditions for and treatment of those in prisons, young offender institutions (YOIs) and immigration detention facilities. HMI Prisons also inspects court custody, police custody and customs custody (jointly with HM Inspectorate of Constabulary), and secure training centres (with Ofsted).

3. HMI Prisons is one of the organisations that deliver the UK government's obligations arising from its status as a party to the UN Optional Protocol to the Convention Against Torture (OPCAT). OPCAT requires state parties to establish an independent National Preventative Mechanism (NPM) to inspect all places of detention. Article 19 (c) of the Protocol sets out the NPM's powers to submit proposals concerning existing or draft legislation.

4. When inspecting establishments, inspectors use detailed criteria, or *Expectations*[1], to assess the treatment and conditions of those being held in police custody. These *Expectations* also offer a guide to inspected organisations as to the standards that we expect to find in these settings, and the sources of information and evidence upon which they will rely.

5. Our relevant expectation falls within the Respect section and relates to the pharmaceutical services provided to prisoners. It states that

    - *Prisoners are cared for by a pharmacy service which assesses and meets their needs and is equivalent to that in the community*

6. This response to the Home Office consultation on the scheduling of tramadol, and a review of exemptions for temazepam prescriptions, under the Misuse of Drugs Regulations draws from evidence generated by our inspections of places of detention.

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[1] http://www.justice.gov.uk/downloads/about/hmipris/police-custody-expectations.pdf

Inspection evidence (supporting information)

HMI Prisons has significant concerns about the perceived excessive prescribing of a number of medications including: tramadol; gabapentin; and pregabalin without appropriate safeguards. Such safeguards include:

- evidence of effective diagnosis;
- treatment of the underlying cause;
- evidence-based prescribing;
- effective communication between all individuals involved in the individual's care e.g. mental health services, clinical substance misuse services and hospital specialist and primary care to ensure prescribing is rationalised and appropriate;
- dynamic risk assessment of the individual, the medication and the environment;
- appropriate review; and
- alternatives to analgesia including psychological interventions, specialist pain management services and physiotherapy.

Inspection evidence suggests that excessive prescribing of such medications has contributed to a significant sub-culture within custodial establishments whereby medication is being diverted from legitimate routes within establishments. However, we have also observed some recent good practice which embraces the safeguards highlighted above e.g. at the Isle of Wight[2] cluster and Full Sutton[3], both establishments took a systematic approach to prescribing high risk medication appropriately.

While we welcome action to address the adverse sequelae of tramadol misuse, there is a requirement to provide additional resources to address the cause of the misuse. Without this, we believe, that those prisoners/ detainees misusing the drug will simply transfer to using a different drug.

Key questions for the proposal on tramadol and Temazepam:

a. In light of the risks of diversion and harms from misuse identified in the ACMD advice which option do you support?

Please tick only one box:

Option 1	Do nothing	
Option 2 **Option 2a**	Full Schedule 3 status for tramadol under the 2001 Regulations (including application of safe custody requirements) and removal of exemptions for Temazepam prescriptions. Schedule 3 status for tramadol under the 2001 Regulations (but **exclude** application of safe custody requirements) and removal of exemptions for Temazepam prescriptions.	
Option 3	Schedule 3 status for tramadol under the 2001 Regulations, but with exemptions from prescribing requirements, similar to Temazepam, and safe custody provisions (No changes for Temazepam).	
Option 4	Schedule 4 Part 1 status for tramadol (No changes for Temazepam).	**x**

[2] http://www.justice.gov.uk/downloads/publications/inspectorate-reports/hmipris/prison-and-yoi-inspections/isle-of-wight/i-o-w-2012.pdf

[3] http://www.justice.gov.uk/downloads/publications/inspectorate-reports/hmipris/prison-and-yoi-inspections/full-sutton/full-sutton-2012.pdf

Please explain why:

The National Institute of Clinical Excellence guidance[4] recognises that tramadol can be an effective medication to prescribe for moderate to severe pain and should be available for use in health settings. However, our inspection evidence suggests that tramadol is overprescribed and not sufficiently regulated in the community which contributes to it being over-prescribed in prison settings. Despite this, it is our belief that schedule 3 appears excessive for the identified harm and would impose requirements in the prison setting that would be excessively costly and time consuming. Further, Schedule 3 status could potentially have a negative impact on prisoner well-being by reducing their access to purposeful activity, due to extended drug administration times.

There is also a risk that less appropriate medication that is easier to manage, may be prescribed which could result in severe adverse outcomes for some prisoners.

Schedule 4 would be easier to manage in a prison setting while also maintaining appropriate safeguards around misuse and diversion.

[4] http://publications.nice.org.uk/opioids-in-palliative-care-safe-and-effective-prescribing-of-strong-opioids-for-pain-in-palliative-cg140

a. b. Do you agree with the impact assessment of option 2? : Place tramadol in Schedule 3 (and remove temazepam prescription exemptions)?

Please tick one box: No
If NO, please explain why:

We do not agree that the monetised costs would be negligible as the costs of additional Controlled Drug Cupboards (CDC), staffing to administer the medication and monitor treatment queues in custodial settings, storage for paperwork related to supply and a move to alternate prescribing have the potential to be extremely significant.

We agree with the key assumption that prescribers may be reluctant to prescribe or reduce the number of prescriptions for tramadol as a result of the change in legal status. However, we disagree that patients will not suffer negative consequences, as a result, as they may be prescribed medications with more damaging side-effects or receive sub-therapeutic treatment with subsequent negative physical, mental and social sequelae.

The identified non-monetised benefit to the main effected groups assumes there will be an automatic resolution of substance misuse as a consequence. In the past this has not been the case, instead new markets have been generated and other drugs substituted which may have greater associated costs.

c. Are you aware of any other impact on healthcare professionals, institutions or industry as a result of the proposal, for example additional costs from specific forms used for private prescribing?
Please tick one box: Yes
Please provide details:

We are concerned that prisoners held in police cells and prisons and detainees held in immigration removal centres (IRC) will be excessively disadvantaged as a result of the proposal.

There is a risk that implications from the proposal could lead to these groups being more directly affected than community groups because an increase in resources will be required to administer Tramadol. For example, in police cells controlled drugs must be administered by a health professional which will require an increase in resources, as many police custody suites do not have health staff on site at all times.

Non-monetised costs include detainee ill health related to changing medication regimes, negative detainee behaviour related to enforced altered medication regime, increased staff stress related to detainee dissatisfaction (impact on sickness levels, recruitment and retention) and increased demand for health services. Additionally, we would predict an increase in complaints and the time taken to manage these.

d. To help inform the full impact assessment please quantify either the:
☐ additional cash cost per month of this proposal to you or your organisation, or
☐ the savings per month of this proposal to you or your organisation.

As an independent organisation we are not able to comment on either the cost or the saving for individual establishments.

e. Do you agree that healthcare organisations or businesses will be able to accommodate tramadol in current storage space?
Please tick one box: No

Please provide details:

The requirement to store Tramadol in a CDC will generate a significant requirement for additional approved storage in all settings.

f. Do you agree with the impact assessment of option 3?

Please tick one box: No

Please provide details:

We are concerned that this option will also excessively disadvantage prisoners held in police cells and prison as well as detainees held in IRCs. As There is a risk that implications from the proposal could lead to these groups being more directly affected than community groups because an increase in resources will be required to administer Tramadol.

We do not agree that the monetised costs would be negligible as the cost of staffing to administer the medication, monitor the prison/IRC treatment queue, storage for paperwork related to supply and the potential move to alternate prescribing will be extremely significant.

As indicated in option two we agree with the key assumption that prescribers may be reluctant to prescribe or reduce the number of prescriptions for tramadol as a result of the change in legal status. However, we disagree that patients will not suffer negative consequences as a result, as they may be prescribed medications with more damaging side-effects or receive sub-therapeutic treatment with subsequent negative physical, mental and social sequelae.

g. Are you aware of any other impact on healthcare professionals, institutions or industry as a result of the proposal?

Please tick one box: Yes

Please provide details:

In police cells and most prisons/IRCs Schedule 3 tramadol would require supervised consumption by two staff which will result in an increase in resources.

Non-monetised costs include: detainee ill health related to changing medication regimes; negative detainee behaviour related to enforced altered medication regime; increased staff stress related to detainee dissatisfaction (impact on sickness levels, recruitment and retention); and increased demand for health services. Additionally, we would predict an increase in complaints and the time taken to manage these.

h. **To help inform the full impact assessment please quantify either the:**

☐ **additional cash cost per month of this proposal to you or your organisation, or**

☐ **the savings per month of this proposal to you or your organisation.**

As an independent organisation we are not able to comment on either the cost or the saving for individual establishments.

i. Do you agree with the impact assessment of option 4?

Please tick one box: No

Please provide details:

We are concerned that this option will also excessively disadvantage prisoners held in police cells and prison as well as detainees held in IRCs. As stated in three, there is a risk that implications from the proposal could lead to these groups being more directly affected than community groups because an increase in resources will be required to administer Tramadol.

We do not agree that the monetised costs would be negligible as the cost of staffing to administer the medication, monitor the prison/IRC treatment queue, storage for paperwork related to supply and the potential move to alternate prescribing will be potentially extremely significant.

As indicated in options two and three we agree with the key assumption that prescribers may be reluctant to prescribe or reduce the number of prescriptions for tramadol as a result of the change in legal status. However, we disagree that patients will not suffer negative consequences as a result, as they may be prescribed medications with more damaging side-effects or receive sub-therapeutic treatment with subsequent negative physical, mental and social sequelae.

j. **Are you aware of any other impact on healthcare professionals, institutions or industry as a result of the proposal?**
Please tick one box: No

Non-monetised costs include: detainee ill health related to changing medication regimes; negative detainee behaviour related to enforced altered medication regime; increased staff stress related to detainee dissatisfaction (impact on sickness levels, recruitment and retention); and increased demand for health services. Additionally, we would predict an increase in complaints and the time taken to manage these.

k. To help inform the full impact assessment please quantify either the:
☐ additional cash cost per month of this proposal to you or your organisation, or
☐ the savings per month of this proposal to you or your organisation.

As an independent organisation we are not able to comment on either the cost or the saving for individual establishments.

Elisabeth Tysoe **9 October 2013**
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