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The Pharmaceutical Services Negotiating Committee

Response to:

Home Office Consultation on the scheduling of
tramadol and a review of exemptions for temazepam
prescriptions under Misuse of Drugs Regulations 2001



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PSNC is pleased to be able to comment on the Home Office consultation on the scheduling of tramadol and a review of exemptions for temazepam prescriptions under Misuse of Drugs Regulations 2001.

PSNC promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health as the body that represents NHS pharmacy contractors. Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.

Executive Summary

PSNC notes that the Home Office states that it is not consulting on views as to whether tramadol should be controlled under the Misuse of Drugs Act 1971, and so we make no comment on that, other than to say that the report of the Advisory Committee on Misuse of Drugs proposes that the control is intended to prohibit possession and supply other than where there is legal authority (for example, where obtained against a prescription).

The majority of the deaths which has prompted the review have occurred where tramadol has been obtained outside of legitimate channels. Whilst no number of deaths is acceptable, it is noteworthy that the number of paracetamol deaths is higher than the number attributable to tramadol, and that is despite the withdrawal of co-proxamol. The Home Office should therefore be careful not to introduce disproportionate measures that could adversely affect legitimate treatment with tramadol under the NHS.

It is said in the report that the risk of death and serious harm caused by tramadol is due to its dual modes of action, and the fact that in overdose the use of naloxone will reduce only the opioid effect, and that the other toxicological factors are unaffected. There is a need to educate prescribers, to ensure that prescribing of tramadol is appropriate, and having regard to the potential risks. Pharmacists, also, would benefit from additional training about this risk factor so that they may better inform patients who present prescriptions, of the care that must be taken with the administration of the drugs, and to recognise signs of overdose. However, it is likely that such education will provide little benefit to the majority of affected persons, who obtain tramadol through non-medical routes.

Our major concerns are that the scheduling of tramadol must be sensitive to the additional burdens that can be caused. There are two main burdens: storage, and compliance with Regulation 15.

The impact assessment erroneously concludes that because pharmacies already have a compliant safe, they will incur no additional costs in storing tramadol. That is an incorrect assumption – there are many different presentations of tramadol, and these different variants mean that most pharmacies will have significant extra demands on secure storage, which cannot be met within current resources.

The requirement to comply with regulation 15 will require a change of practice for prescribers, but it will also mean pharmacists must verify that the prescription is complete (because of their corresponding duty under regulation 16). We know from other exercises where drugs have been elevated to higher levels of control, that prescribers take time to change their systems and to become fully compliant. In the meantime, pharmacists reluctantly, must refer incomplete prescriptions back to the prescriber for amendment. This is wasteful of resources and causes delay to the treatment of patients. In the case of tramadol, patients are suffering from moderate to severe pain, and every effort

should be made to ensure that unnecessary legislative barriers do not get in the way of their treatment.

PSNC therefore believes that adding to Schedule 4 would provide sufficient control, and would avoid the problems with storage and regulation 15 highlighted above.

Finally, we must comment on the consultation itself. Several of the questions ask for reasons. If we take question 'b' as an example, this requires a response about safe custody of tramadol, and regulation 15 prescription writing requirements for both tramadol and temazepam. It is impossible to provide sufficient meaningful feedback in support in 100 words or less, and the imposition of this arbitrary word limit implies that the Home Office has no interest in hearing the reasoned views of consultees. We hope that this perception is wrong, and that the Home Office welcomes and takes account of our response.

Consultation Questions

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

Option 4

The majority of harm arises from non-prescribed tramadol. It is disproportionate to impose Sch3 to achieve ACMD's purpose of controlling possession and supply.

Tramadol is available in many presentations requiring large amounts of storage space. ACMD presents no evidence of diversion from pharmacy break-ins, and as tramadol is available via the internet, an abuser would obtain from that source, rather than commit burglary.

Prescribing practice must recognise the risks in overdose, and Pharmacists must be able to counsel patients appropriately so training is appropriate. Legitimate prescribed supplies are not the main target of the proposal to control under the Act

b. Do you agree with the impact assessment of option 2?

No.

The impact assessment considers costs of safe custody would apply only if the pharmacy does not currently have a compliant safe. According to WWW.NHS.UK, Tramadol is available in 14 different presentations, and several brand names. Pharmacies would expect to hold several of these. The space available in existing cabinets would be insufficient to contain this stock.

Reg15 proposals will increase the burden on pharmacists checking compliance and referring back for completion whilst prescribers amend practices. Sch3 drugs cannot be prescribed under electronic prescription service. Supplementing electronic messages with paper prescriptions is an additional burden for prescribers, and inconvenient to patients.

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?

Yes

As there are currently 11.1 million doses prescribed, it is reasonable to presume that there will be some demand for private prescriptions. PSNC does not have data on private prescribing, but for any such prescriptions there will be additional handling costs in pharmacy to segregate these forms for forwarding to the NHSBSA. Although this activity is already carried out for other privately prescribed controlled drugs, this marginal increase in workload should be factored into the impact assessment.

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.

We are unable to provide a cost per month – because the cost associated with purchasing and installation of an additional compliant safe is a one off as opposed to monthly cost.

PSNC represents pharmacies in relation to their NHS services, and therefore does not have data relating to the workload associated with private prescriptions.

e. Do you agree that healthcare organisations or businesses will be able to accommodate tramadol in current storage space?

No.

According to WWW.NHS.UK, Tramadol is available in 14 different presentations, and under several brand names. Pharmacies would expect to hold several of these. The space available in existing cabinets would be insufficient to contain this additional stock.

There are in excess of 7 million prescriptions issued annually for tramadol. The storage of dispensed items pending collection by the patient will add considerably to the storage burdens, where the dispensed stock as well as replenishment stock will both need secure storage.

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

No.

The impact assessment does not recognise the costs to pharmacists of verifying that the regulation 15 requirements have been met, and of referring non-compliant prescriptions back to the prescriber. Increasing the level of control for a drug that is already being prescribed under only 'POM' control, will inevitably lead to errors during a transitional period until prescribers are accustomed to the new controls.

The impact assessment also fails to recognise the delays to treatment that will be caused by such referrals back to the prescriber for completion of prescriptions.

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

No,

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.

Please provide details of cost per month:

PSNC does not have available data on the number of prescriptions that will be inadequately written, and so the resources necessary to remedy incorrectly written prescriptions will need to be quantified and taken into consideration.

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

Yes.

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

No

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.

Please provide details of cost per month:

PSNC is unable to provide data of costs associated with scheduling under option 4.

Demographic questions

23. To assist in analysing the responses the Home Office will be grateful if you could answer the following demographic questions;

Please tick applicable box

i. Are you responding as a:

Other (Please specify below)

NHS Representative body

ii. Are you a;

NHS practitioner (organisation)

iii. Which region are you responding from?

England