ROYAL PHARMACEUTICAL SOCIETY

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

Dear Sir/Madam,

The Royal Pharmaceutical Society is pleased to have the opportunity to respond to your consultation on the scheduling of tramadol and a review of exemptions for temazepam prescriptions under Misuse of Drugs Regulations 2001.

This is a complex area which and we have consulted with specialists from the pharmacy profession in order to give you expert opinion on your consultation questions.

Q1 In light of the risks of diversion and harms from misuse identified in the ACMD advice which option do you support?

We support 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).
Please explain why:

The Royal Pharmaceutical Society (RPS) is supportive of the need to control tramadol under the Misuse of Drugs Act 1971. The evidence from the Office for National Statistics and local prescribing data from Health Organisations confirms that the prescribing of this drug is now in need of closer monitoring, as it is subject to abuse and dependence with prescribing rates both in primary and secondary care steadily increasing from 2007.

Our concern is in obtaining the correct schedule for the drug, one which will have an effect on reducing prescribing for patient safety reasons and reflect the logistics of applying the safe custody provisions to tramadol. The introduction of safe custody provisions will have a significant impact on the operation of community and hospital pharmacies and are not warranted for patient safety reasons, namely the drug is over prescribed , has a recognised side effect profile , it is less effective than many other analgesics available and it is liable to misuse.

Storage issues
There are currently six different dosage forms of tramadol from many manufactures; it is prescribed generically and by branded generics. This combination of dosages and products

requires a pharmacy to hold significant levels of stock and to re-site this stock to a controlled drugs cupboard would be very difficult for no additional patient safety benefit.

On average a community has 2 shelves currently being used from tramadol products, so any change in storage requirements without a corresponding change in prescribing practice would require most pharmacists to have capacity issues with their current CD cupboards.

Within the hospital environment, tramadol is stored in a number of settings, including dispensing Robots, the ward cabinets, automated dispensing systems and on open shelves. If storage requirements were to be introduced, it would cause issues at all storage points, especially at ward level where there are usually small CD cabinets. Additionally it may affect the process and increase the time to discharge patients, as take home medicines that contain Controlled Drugs with safe storage requirements are subject to additional checks and recording processes (not supplied in the same manner as other medicines).

Within care homes, additional safe storage requirements will be burdensome and may elevate the status of tramadol amongst staff, to a drug with the potential for abuse.

Within a secure environment – we would like to draw your attention to the separate response submitted by the Secure Environment Pharmacist group which we would endorse.

Any benefit from reclassifying tramadol will be achieved by reducing prescribing, and by ensuring it is prescribed appropriately and according to the WHO Analgesic Ladder. We would advocate more monitoring for tramadol prescribing and patient and prescriber education in the use of alternative analgesics. The introduction of storage requirements will have no effect on patient safety or its prescribing profile but may adversely make it more “popular” as a drug of abuse as there can be a perception that drugs that have to be stored securely are more appealing for diversion and abuse.

We are unaware of any community pharmacy robberies that have specifically targeted tramadol or the diversion of tramadol by pharmacy staff, therefore the need for safe storage would impact negatively with no corresponding gain.

We would therefore request reclassification to schedule 3, with a review of this arrangement in 12-24 months time.

In respect to the proposed changes to temazepam will believe the reintroduction of prescription writing requirement will have a negative effect for no significant gain or benefit to patient safety.

The consultation paper makes the assumption that all prescription are now computer generated, whilst this may be accurate for primary care it is not yet the case in secondary care and for GP prescribing outside of their surgery or out of hours, both situations where temazepam is often prescribed. Additional computer generated scripts are not the norm in many mental health trust in England, where temazepam prescribing is justifiably high.

We would there conclude that within the secondary care setting, reintroducing the prescription writing requirements for temazepam will have an impact , however the degree of that impact we have not been able to gauge at this time.

b. Do you agree with the impact assessment of option 2?
No

The scale and monetised cost have not included the potential purchases of new CD cabinets for storage of tramadol within all settings where tramadol is dispensed. This cost could be considerable across health organisations.

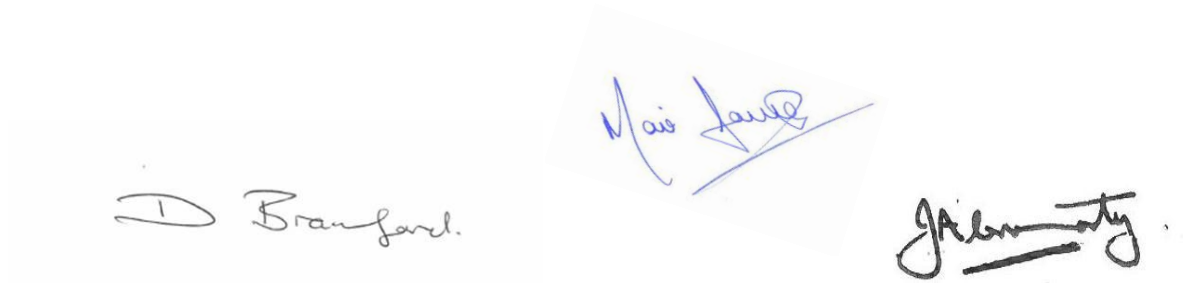
e. Do you agree that healthcare organisations or businesses will be able to accommodate tramadol in current storage space?
No
See response to Q1

f. Do you agree with the impact assessment of option 3?
No

We believe the benefits have been overstated. The aim for any benefit from reclassification of tramadol should be patient safety and to reduce the prescribing of the drug and the impact assessment acknowledges that prescribing will rise; hence the benefits have been overstated.

These issues should be considered further and we are happy to discuss if we can be of assistance.

Best regards,



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About us

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors and specialisms of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

Leadership, representation and advocacy: Ensuring the expertise of the pharmacist is heard by governments, the media and the public.

Professional development, education and support: helping pharmacists deliver excellent care and also to advance their careers through professional advancement, career advice and guidance on good practice.

Professional networking and publications: hosting and facilitating a series of communication channels to enable pharmacists to discuss areas of common interest, develop and learn.