PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

18 September 2015

Associate Professor Cynthia Darlington
Chair, Expert Advisory Committee on Drugs

c/- Hannah Hoang
Office of the Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
Wellington, 6145
via email: Hannah_hoang@moh.govt.nz

Dear Associate Professor Darlington,

Proposed Classification of Tramadol as a Class C5 Controlled Drug under the Misuse of Drugs Act 1975.

Thank you for the opportunity to submit comments on the potential impact of the proposed classification to pharmacy practice.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,000 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines

Regarding the specific questions asked in the consultation, The Pharmaceutical Society would like to note the following comments for consideration:

1. Whether the proposed schedule of tramadol is appropriate.
Yes. The Pharmaceutical Society accepts the reasons for the proposed C5 classification of tramadol, and that the risks and potential adverse outcomes along with reports of oversupply and abuse/misuse does support this classification change. However our support of the proposal is tempered by our concerns outlined below.

2. The estimated costs if tramadol is classified as a class C5 Controlled Drug (CD).
We are not aware of any effect on costs for pharmacists if tramadol was classified as a C5 Controlled Drug.

Medicines classified as a Class C5 CD do not require storage in a safe, are not required to be recorded in a CD Register, and a 3 month period of supply is permitted when prescribing. Therefore we do not anticipate this adversely affecting pharmacies with respect to cost.

3. Any other concerns in relation to the scheduling of tramadol as a Class C5 Controlled drug.

Level 10, Grand Arcade Tower, 16-20 Willis Street, PO Box 11640, Manners Street, Wellington, 6142, New Zealand
TEL 04 802 0030 **FAX** 04 382 9297 **EMAIL** p.society@psnz.org.nz **WEB** www.psnz.org.nz

While The Society supports the proposal to classify tramadol as a Class C5 CD, we would like to raise a number of issues for the Ministry, EACD and/or Minister to consider. These comments have come through feedback from pharmacists in a wide range of practice areas including community, hospital and primary-care practice as well as pharmacist prescribers. The comments support some of the reasons for the proposed classification change. However, also very importantly, these highlight that a change in classification alone is not enough to address the concerns with tramadol use and misuse.

A) Effect on Pharmacist Prescribers' Practice

Changing the classification to C5 means that Pharmacist Prescribers would **NOT** be permitted to prescribe tramadol **UNLESS** an amendment to the Misuse of Drugs Regulations was made to insert tramadol into Schedule 1B – the schedule of "Controlled drugs that designated pharmacist prescribers may prescribe".

Feedback from some pharmacist prescribers has been that they are already very judicious in their use of tramadol due to concerns with adverse effects, misuse and clinical effectiveness/place in therapy considerations – indeed all the reasons for the proposed classification change.

Should the proposal to classify as C5 be accepted, The Society **very strongly recommends** that the amendment to add tramadol to Schedule 1B be enabled at the same time as the change in classification.

> **However**, while we acknowledge that this is not necessarily within the scope of this consultation, the proposal to classify tramadol as a Class C5 controlled drug once again highlights the 3-day period of supply restriction placed on controlled drug prescribing by our Pharmacist Prescribers in Misuse of Drugs Regulation 21(5)(b). The Pharmaceutical Society contests that this is unreasonably restrictive and does not allow pharmacist prescribers to operate at the top of their scope, restricts practice from clinical areas where prescribing of controlled drugs is required, and has a negative impact on the development of this important specialised area of the health workforce. The Pharmaceutical Society **strongly recommends** that Reg 21(5)(b) and Schedule 1B of the Misuse of Drugs Regulations are revoked, and that Pharmacist Prescribers are recognised in the regulations in the same manner as Nurse Practitioners in terms of period of prescribing supply regulated by Controlled Drug Class and choice of agents appropriate to scope.

We note that a change to a Class C5 CD would also mean that midwives and designated prescriber nurses would no longer be permitted to prescribe tramadol unless similar amendments to their prescribing schedules occurred. Feedback from pharmacists has explained that some midwife prescribing of tramadol occurs in both primary and secondary care settings, therefore the effect of classification change on scope of practice should be considered and communicated clearly.

B) Hospital Recording and Storage of Tramadol

Feedback from hospital pharmacists has noted that **some** DHBs treat tramadol similar to benzodiazepines in their recording and storage. That is, while there is no legal requirement to, some hospitals choose to make benzodiazepines a "recorded drug" – where transactions are recorded in a "register" comparable to the "Controlled Drug Register" defined in the Misuse of Drugs Act and Regulations.

In communicating the outcome of this proposal and in enforcing the decision, The Society recommends that the communications and any related resources clarify the legal requirements for recording and storage of Class C5 CDs; and in doing so acknowledging that some hospitals treat benzodiazepines as a "recorded medicine" and that others may wish to include tramadol with these medicines to help curtail diversion from within the hospital system – which does seem to be apparent.

C) Optimisation of Prescribing

A number of pharmacists have provided us with feedback and impressions on how prescribing of tramadol is frequently suboptimal, noting: inappropriate doses, inappropriate periods of supply/quantities, the presence of contraindications or interactions, and unsuitable choice of tramadol as part of pain management plan in individuals.

Some pharmacists have commented how they believe doctors seem "complacent" in prescribing tramadol, perhaps through lack of it being a controlled drug or are complacent about adverse effects. One pharmacist felt that some 'easily persuaded' doctors will freely prescribe 50-100mg to make drug seekers "go away". Prescriptions for inappropriate concurrent use of tramadol with codeine, oxycodone and/or serotonergic agents is very common (secondary and primary care prescriptions).

Reasons for the proposed classification included risks of harm, dependence, oversupply and abuse/misuse. Therefore in communication the outcome of this proposal, The Society recommends that the Ministry and/or other appropriate body (eg. pain specialists) provide prescribers with clear guidelines on the use of tramadol – targeted at prescribers in all areas of practice, including emergency departments, dentists, general practitioners etc. Each face their own pressures for prescribing. Such guidance should explain appropriate use, dosing, place in therapy, contraindications, interactions, adverse effects (relating to pharmacology and risk of serotonergic adverse effects), risk of misuse and dependence, appropriate periods of supply and avoiding use in the elderly. Would recommend this be a targeted piece of work developed by appropriate specialists.

A number of pharmacists have commented that their impression is that prescribers do not necessarily understand that benzodiazepines are controlled drugs. The restrictions on period of supply that occurs with Class A or Class B CDs is not present. It's felt that a conscious decision about appropriate periods of supply for the clinical need is not always made. Therefore in announcing the outcome of this proposal, The Society recommends including a description of the Class C classification of controlled drugs, the monitoring and controls around them and linking this to the reasons for making tramadol a Class C5.

D) Misuse / Abuse of Tramadol

Feedback from pharmacists has described a very definite population of patients who are dependent on or misuse tramadol. Comments have raised a number of factors contributing to this including inappropriate periods of supply prescribed, poor review of patients, and patient confusion over self-management when a number of analgesics are prescribed concurrently – particularly with discharge or emergency department prescriptions from hospital. A number of pharmacists have commented that tramadol is very definitely being accessed illicitly and are misusing prescriptions or 'doctor shopping' to access it. It has a reported street value.

One specialised pharmacist working in mental health noted that for the "addicts", tramadol is not reported on a standard urine drug screen – so they look "clean". It can be tested for, but a specific request must be made to the laboratory to test for tramadol.

One specialised pharmacist working in a Community Alcohol and Drug Service has commented that the abuse / misuse potential of tramadol (in general) is seriously understated – seeing people with primary cases of tramadol dependence. She also felt the incidence of serotonin syndrome with this drug in conjunction with other serotonergic medications is a lot more prevalent than is commonly understood. Something that has been echoed in feedback from a considerable number of pharmacists in community and hospital practice who intervene when they see such co-prescribing.

Inappropriate quantities of tramadol being prescribed has been raised as an issue extensively by pharmacists who are dispensing these prescriptions. Together with excessive doses of tramadol being frequently prescribed (exceeding the recommended daily maximum of 400mg), these factors contribute to the risk of misuse or dependence occurring.

Concluding comment

There does seem to be an appropriate place for tramadol in pain management, however this, along with the extensive contraindications, adverse effects, interactions and risk of misuse appears to be grossly misunderstood by prescribers in all areas of practice; with the exception of pharmacist prescribers we would contend, who have higher levels of awareness of the clinical issues related to tramadol use.

The Society therefore **strongly recommends** that any announcement to classify tramadol as a Class C5 controlled drug be used as an opportunity for education. As a change in classification alone will not address those risks and concerns put forward as reasons for classifying tramadol as a Class C5 controlled drug.

Thank you for consideration of this submission. I would be happy to discuss any aspect of this submission further, if required.

Yours sincerely,

Bob Buckham BPharm, PGCertPharm, PGDipClinPharm, MPS, ANZCP, RegPharmNZ
Chief Pharmacist Advisor