

[medicines.scheduling@tga.gov.au](mailto:medicines.scheduling@tga.gov.au)

## **RE: Proposed amendments to the Poisons Standard - ACMS meeting, November 2016**

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 4,400 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a strong base of members practicing in public and private hospitals and other health service facilities.

SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. SHPA believes that any changes to the scheduling of medicines should be driven and underpinned by the principles of consumer safety and quality use of medicines.

SHPA has the following comments to make with respect to proposed amendments to the Poisons Standard.

### **Brivaracetam**

Support the Appendix K entry for brivaracetam.

### **Follitropin delta**

Support the inclusion of follitropin delta in Appendix D, Item 1 - Poisons available only from or on the prescription or order of an authorised medical practitioner.

### **Melatonin**

SHPA does not support the proposed amendment for preparations containing 1 mg or less of melatonin to be exempt from scheduling. Melatonin is indicated for primary insomnia, a condition that should be treated and managed by health professionals. This proposal would lead to melatonin being available to consumers without consultation with a health professional for diagnosis and to assess appropriateness of therapy, and is fundamentally in contrast to quality use of medicine principles.

### **Panobinostat, ceritinib, olaparib**

Support the Appendix L entry, with warning statement 62 – 'Do not use if pregnant' for these three medicines.

### **Paracetamol compounded with caffeine**

SHPA does not support paracetamol compounded with caffeine to be exempted from scheduling in any form. SHPA is concerned that a combination product that contains two medicines with well documented adverse effects – in particular hepatotoxicity in paracetamol overuse – and that are known to be used inappropriately by consumers, will be made more easily accessible without access to professional advice and counselling by a pharmacist.

### Vardenafil

SHPA does not support a new Schedule 3 entry for vardenafil in oral preparations containing 10mg or less per dosage unit in packs containing not more than 8 dosage units. Vardenafil can prolong QT intervals and increase the risk of arrhythmias, and its use is also cautioned in the setting of hepatic impairment. SHPA does not believe that pharmacies in the community setting have the adequate resources to screen for these risks.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership on [jdeweaver@shpa.org.au](mailto:jdeweaver@shpa.org.au) or (03) 9486 0177.

Yours sincerely,

A handwritten signature in black ink that reads "K. Michaels". The signature is written in a cursive, flowing style.

Kristin Michaels  
Chief Executive Officer