

**10 May 2018**  
**Advisory Committee on Medicines Scheduling**  
**Therapeutic Goods Administration**

**Consultation: Invitation for public comment - ACMS meeting, June 2018**

*A request has been made to:*

- *Create a new Schedule 3 entry for sildenafil in oral preparations containing 50 mg of sildenafil per dosage unit in packs containing not more than 8 dosage units;*
- *To include sildenafil in Appendix H to permit advertising; and*
- *To include sildenafil in Appendix M to provide additional controls or supply requirements to allow sildenafil to be supplied by a pharmacist.*

We support the current scheduling for sildenafil and oppose the proposed changes. A search of the NSW Poisons Information Centre database (takes approximately half of the national call volume) 6/1/14 – 8/5/18 was performed for PDE-5 inhibitor exposures and is summarised below.

There were 98 unique calls relating to sildenafil, 46 to tadalafil and 6 to vardenafil. The table indicates a summary of the type of exposure and number of calls. Of note for the cases other than deliberate self-poisoning, 72 cases were managed by a hospital and 7 by a GP indicating a high rate of hospital referral compared to other pharmaceuticals. This is pronounced in accidental paediatric ingestions with 56% managed in hospital.

Accidental paediatric ingestion	59
Adverse drug reaction	37
Intentional: deliberate self-poisoning	22
Unintentional: Therapeutic error	18
Drink spiking	11
Intentional misuse: additional doses taken	9
Overseas medication use	6
Multiple PDE5-inhibitor use	5
Intentional misuse: use with alkyl nitrite	2

NB: Multiple types of exposure are possible for each call.

This data indicates the potential harms and misuse of PDE5 inhibitors such as sildenafil which would be expected to increase with more widespread availability without a prescription. We would welcome a more detailed analysis of the national Poisons Information Centre data and would be happy to facilitate this.

Yours sincerely,



*NSW Poisons Information Centre*  
*Sydney Children's Hospital Network (Children's Hospital at Westmead)*