Part 2

Public submissions on proposed amendments to the *Poisons Standard*

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current *Poisons Standard* and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice. Such a notice relating to the scheduling proposals initially referred to the July 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #21), the Advisory Committee on Chemicals Scheduling (ACCS #20), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #16), was made available on the TGA website on 17 May 2017 and 7 June 2017, closing on 15 June 2017 and 7 July 2017 respectively.

Public submissions received on or before these closing dates (15 June 2017 and 7 July 2017) are published here in accordance with regulation 42ZCZL. Also in accordance with the regulation 42ZCZL, the Secretary has removed information that the Secretary considers confidential.

Under regulation 42ZCZN of the Regulations, the Secretary, after considering the advice or recommendation of the expert advisory committee, must (subject to regulation 42ZCZO) make an interim decision in relation to the proposed amendment. If the interim decision is to amend the current *Poisons Standard*, the Secretary must, in doing so, take into account the matters mentioned in subsection 52E(1) of the Act (including, for example, the risks and benefits of the use of a substance, and the potential for abuse of a substance) and the scheduling guidelines as set out in the *Scheduling Policy Framework for Chemicals and Medicines* (SPF, 2015), available on the TGA website.

Under regulation 42ZCZP of the Regulations, the Secretary must, among other things, publish (in a manner the Secretary considers appropriate) the scheduling interim decision, the reasons for that decision and the proposed date of effect (for decisions to amend the current *Poisons Standard*, this will be the date when it is expected that the current *Poisons Standard* will be amended to give effect to the decision). Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must invite the applicants and persons who made a submission in response to the original invitation under paragraph 42ZCZK(1)(d), to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the July 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #21), the Advisory Committee on Chemicals Scheduling (ACCS #20), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #16) was made available on the TGA website on 15 September 2017 and closed on 3 October 2017. Public submissions received on or before this closing date will be published on the TGA website in accordance with regulation 42ZCZQ of the Regulations.

Privacy statement

The Therapeutic Goods Administration (TGA) will not publish information it considers confidential, including yours/other individuals' personal information (unless you/they have consented to publication) or commercially sensitive information. Also, the TGA will not publish information that could be considered advertising or marketing (e.g. logos or slogans associated with products), information about any alleged unlawful activity or that may be defamatory or offensive.

For general privacy information, go to https://www.tga.gov.au/privacy. The TGA is part of the Department of Health and the link includes a link to the Department's privacy policy and contact information if you have a query or concerns about a privacy matter.

The TGA may receive submissions from the public on a proposed amendment to the Poisons Standard where there has been an invitation to the public for submissions on the proposal in accordance with the *Therapeutic Goods Regulations 1990*. These submissions may contain personal information of the individual making the submissions and others.

The TGA collects this information as part of its regulatory functions and may use the information to contact the individual who made the submissions if the TGA has any queries.

As set out above, the TGA is required to publish these submissions unless they contain confidential information.

If you request for your submission to be published in full, including your name and any other information about you, then the TGA will publish your personal information on its website. However, if at any point in time, you change your mind and wish for your personal information to be redacted then please contact the Scheduling Secretariat at medicines.scheduling@health.gov.au so that the pubic submissions can be updated accordingly.

Please note that the TGA cannot guarantee that updating the submissions on the TGA website will result in the removal of your personal information from the internet.

Please note that the TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

Submission

July 2017 meeting of Joint Advisory Committees on Chemicals and Medicines Scheduling (Joint ACCS-ACMS)

Purpose

The Toxicology and Poisons Network Australasia (TAPNA) makes this submission in relation to items referred by the Delegate for scheduling advice to the July 2017 meeting of the Joint Advisory Committees on Chemicals and Medicines Scheduling.

TAPNA is the professional society of health care professionals working within the fields of poisons information and clinical toxicology. It includes all Australian Poisons Information Centres as well as medical specialists and trainees working in hospital based clinical toxicology units.

Recommendations

Phenibut. TAPNA Inc. support the scheduling of phenibut in Schedule 9

Specific comments

There is no defined therapeutic need or role for phenibut in Australia. While it as marketed on the internet for sale as a dietary supplement it is clear that its major use is a recreational drug (https://erowid.org/experiences/subs/exp_Smarts_Phenibut.shtml). {Owen 2016}
Over the past 4 years all Australian Poisons Information services and hospital based clinical toxicology treatment centre have identified an increasing number of cases of acute toxicity some of which have been analytically confirmed. {Downes 2015}

Phenibut represents a significant risk in overdose to the individual. In acute intoxication psychomotor impairment and delirium are common, patients with larger ingestion have required intubation and ventilation.
Cessation of chronic use is associated with withdrawal syndrome which is consistent with its known pharmacological actions

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Dr Michael Downes
Emergency physician/Clinical Toxicologist
Calvary Mater Newcastle, NSW
Consultant, NSW Poisons Information Centre

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Yours sincerely

[redacted]

Michael A Downes
Interim President, TAPNA Inc

To whom it may concern,

I am writing to you in relation to the scheduling of the substance Phenibut. I wholeheartedly and strongly disagree with the proposed scheduling of Phenibut into Schedule 9 and have concerns with it being scheduled into Schedule 4 with an Appendix D, Part 5 entry.

Phenibut is unique and extremely beneficial substance for many which I personally have experienced a tremendous benefit from and it has improved my quality of life like no other medication or supplement. It is very effective for depression and for anxiety with a strong effectiveness for social anxiety as well as for insomnia and has many other benefits.

Phenibut is actually prescribed in Russia to treat a wide range of conditions such as depression, anxiety, insomnia, to reduce stress and posttraumatic stress disorder to name a few.

As mentioned in your Substance Summary it is a Nootropic which makes it a very beneficial substance.

Phenibut is relatively unknown in the western world and there are very few toxicity reports which makes me question the 'serious public health concerns'.

It concerns me greatly that you are thinking about scheduling Phenibut when no other country in the world has scheduled it (as noted in the Substance Summary) except for Russia where is it prescribed.

Yes there are side effects and increasing the dose increases these side effects but this is the same for every supplement and medication. The positives far outweigh the negatives and this must be taken into consideration.

To put Phenibut into Schedule 9 would be extremely ignorant of the tremendous health benefits and would be completely detrimental and devastating to the people who it helps every single day. If you are considering putting Phenibut into Schedule 9, then alcohol which also acts on the GABA receptors would immediately need to be put into Schedule 9 as it poses extreme health concerns due to 15 Australians dying each day and 430 Australians being hospitalised, yet alcohol is not scheduled at all and has no medicinal use.

To put Phenibut into Schedule 4 with an Appendix D, Part 5 entry is more sensible but it is also concerning as it would be near impossible for anyone to be prescribed it, not to mention the increased financial costs to afford it, and it would put my health and many others in immediate risk as it substantially improves my quality of life.

My recommendation is to leave it unscheduled as no other countries have scheduled it and in keeping things relative the serious public health concerns are unfounded. *If* Phenibut must be scheduled then please considering scheduling it in Schedule 3 and please not any higher than Schedule 4 no Appendix.

This decision will have catastrophic ramifications on my health and well-being and for many others so please do not make this decision lightly and please consider my first recommendation. We all only live once and if something makes a difference to a person's wellbeing then it's a human right to have that something kept available to them.

I have included a summary on the next page of what impact Phenibut has on my life. As you can see, this substance is very important to my health and well-being.

Thank you for taking the time to read my submission.

I have been suffering from the debilitating condition Chronic Fatigue Syndrome/a Lyme-like illness since the age of 19 (I am now 27 years of age). This illness has given me symptoms such as debilitating fatigue, no energy, crashing from exerting myself too much mentally or physically, muscle aches, joint pain, depression, anxiety, headaches, poor sleep, insomnia, digestive issues, exercise intolerance and post-exertional malaise, low physical and mental stamina and stress intolerance to name a few.

I have been hospitalised, bed-ridden and house bound and barely been able to work and have any quality of life. I have seen many doctors and been through many treatments and tried many supplements with nothing really helping and only continuing my suffering. My only success has been in the last 3 years with the diagnosis and treatment of Lyme disease/a Lyme-like illness. As much as a break-through as this has been, it has only stopped the muscle aches and joint pain as well as significantly stopping but not completely stopping the crashing and only taking an edge off the fatigue. All my other symptoms remain.

Along my journey of trying to rediscover my health, I have tried many, many supplements with only a few having any kind of benefit more than a placebo, until I discovered Phenibut.

The first thing I noticed is that it provided a mood boost and promoted a positive outlook on life and it significantly reduced my anxiety. I was all of a sudden feeling alive again and the day did not seem daunting, as all of a sudden I had more energy, I wasn't feeling sick from exerting myself and my anxiety was much more manageable. This enabled me to have my first productive 'normal' days in many years and not only that it enabled me to sleep deeply for the first time in many years.

All of a sudden I had genuine hope for the first time in over five years. As I trialled the appropriate dose for myself and the results kept working, I started to realise that after all these years I had finally found a key to my health. I noticed a significant improvement in my quality of life and my well-being. I had more physical and mental energy which significantly reduced my headaches, my anxiety was significant reduced (especially my social anxiety) and my tolerance to stress increased. I was finally sleeping better and naturally my mood improved due to my overall wellbeing. I finally felt the closest I have been to 'normal' in over five years and finally had hope and felt confident that I now had a future and could manage life.

I have now been using Phenibut for nearly a year and it has literally been a life-saver for me and is working just as it did the first time I came across it. While it is not a cure, it has significantly reduced my symptoms and made me a much more functional person. I am still not 100% but I am now able feel relatively well most of the time and am able to manage my illness as best I can. I can also now do things I could only dream of years ago such renting a home, travelling overseas, working part-time in an office, actually getting through and participating in a 'normal' day and most importantly having a life and a future.

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Therapeutic Goods Administration

Joint Advisory Committees on Chemicals and Medicines Scheduling (Joint ACCS-ACMS)

Consultation Submission
Phenibut: CAS Number: 1078-21-3

Dear Delegates of the Joint ACCS-ACMS,

Thank you for the opportunity to make a submission to your joint committee meeting, regarding amendments to the scheduling of Phenibut (CAS Number: 1078-21-3).

I write to you as a consumer of this product, with no affiliations to any businesses, associations, organisations or groups with interests in this field. All statements contained in this submission are personal in nature only.

To begin, it is appropriate and necessary to provide medical information to establish the context for my consumption of Phenibut, in accordance with the *Therapeutic Goods Act, 1989* Section 52E (1): (a) *the risks and benefits of the use of a substance*; and (b) *the purposes for which a substance is to be used and the extent of use of a substance*.

I have been diagnosed with a sleeping disorder, which impacts significantly on my ability to function effectively on a daily basis. Idiopathic Hypersomnia (IH), also known as Primary or Central Hypersomnia is poorly understood, and is closely related to Narcolepsy. As the name indicates, there is no known cause (idiopathic) for the excessive sleep and excessive sleepiness (hypersomnia) of sufferers. More specifically, I have the form of IH labelled “with long sleep time”. This means that the main sleep period lasts for 10 or more hours. Other symptoms include: sleep is not refreshing; Sleep Inertia (also known as sleep drunkenness); and Excessive Daytime Sleepiness (EDS). In current research, it is understood that IH is distinctly different from Narcolepsy (without cataplexy), but that both conditions may be part of a broader spectrum. The role of hypocretin in Narcolepsy patients does not appear to be a factor in IH. It is possible that GABA and/or GABA receptors may be involved. Speculation is that an unknown “somnogen” is responsible for over-stimulating the GABA-A receptor, the resulting interactions with chloride and potassium, causing hyperpolarisation within the neuron.

Due to its idiopathic nature, there are currently no effective treatments for IH. At best, patients may find relief from Excessive Daytime Sleepiness (EDS) with Central Nervous System (CNS) stimulants and wakefulness-promoting agents, such as dex-amphetamine, modafinil or armodafinil. Flumazenil is offering hope, but delivery is proving to be a barrier to its production (a subdermal implant is not a feasible method). It is clear that sufferers of IH are severely under-treated. While my EDS was greatly reduced by the medication prescribed, I still had extreme difficulty transitioning from sleep to wake. It is within this context that I dedicated many hours of personal research to finding alternatives that could assist me to function effectively. It was during my investigation of a product called Xyrem (for Narcolepsy) that I came across a post in a small

internet forum, where phenibut was described, and was declared “better” than other prescribed medications. Upon further investigation around the GABA-A and GABA-B receptors, and the hyperpolarisation theory, I discovered that phenibut was a GABA-B receptor agonist. With no medical training whatsoever, it seemed logical that stimulating the GABA-B receptor would increase the flow of potassium out of the neuron, keeping better pace with the GABA-A receptor letting chloride in. I decided to try phenibut.

Due to its long action time, I decided to take a small dose of phenibut before bed, hoping that it would become effective during the night, and have an impact on the sleep inertia that was stealing 1 ½ hours of my time each morning. After that first dose, I indicated to my partner that I didn’t think that it had “done anything”. His reply was definite: “Are you kidding? You can construct a sentence!” It was obvious that phenibut had a significant impact upon the ‘untreatable’ sleep inertia.

I have consumed phenibut a few days per week to assist my functionality. With phenibut, I am better able to get to work on time. As a teacher, being reliably on time is very important, and flexible hours are not possible. Consuming phenibut means that I am able to continue to work at all.

My profession should also indicate to you some of my core values, and an understanding of governmental systems and policy. It is not my intention to argue against regulation of substances which present the potential for harm. I do, however, intend to bring your attention to less-known uses of phenibut.

In amending the scheduling of phenibut to Schedule 4 or Schedule 8, Section 52E (1) (d) must be considered: *the dosage, formulation, labelling, packaging and presentation of a substance*. The Proposed Amendments, the Key uses/expected use states: *Marketed to relieve anxiety and depression, improve sleep and enhance cognition.* I have outlined above the effect of phenibut upon symptoms of IH. In rescheduling, its use for *anxiety and depression* and [*improving*] *sleep*, would mean that I, and other IH sufferers, would need to be prescribed phenibut ‘off-label’, thereby making it a more difficult decision for health professionals. Further, as a Schedule 8 substance, obtaining Pharmaceutical Benefits Scheme (PBS) approval may be necessary, possibly requiring the services of a Specialist Medical Professional. Some sufferers may find this added cost to their health care unsustainable.

A minor added advantage of phenibut to me, is that it is available in a dissolvable powder. As I am unable to take tablets/capsules, this is helpful because, unlike my medication, I do not need to crush it. Rescheduling this substance would likely result in pharmaceutical companies reformulating it into a tablet/capsule.

In closing, I reiterate that I am not presenting an argument either for, or against the rescheduling of phenibut. Rather, I intend to bring your attention to some lesser-known uses of phenibut, and the possible implications. I would like to thank the Delegates for their consideration of this submission, and await the outcome of the Joint Meeting.

[redacted]

Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

Monday, 10 July 2017

The Delegate,
ACMS and ACCS
TGA
Department of Health

To whom it may concern

<u>Proposed scheduling change:</u> Due to serious public health concerns, the delegate is considering scheduling phenibut in Schedule 9 or Schedule 4 with an Appendix D, Part 5 entry. Consideration will also be given to whether a group entry is appropriate.

Summary: ASCEPT supports this decision and does not have a preference between Schedule 9 or 4

The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) is the professional and independent Society in Australia and New Zealand with expertise in the use and toxicity of medicines and chemicals.

Our members have reported an increasing number of cases of suspected phenibut use, misuse and harm. Cases are considered suspected given the lack of a readily available assay to confirm contents of products, or its presence in blood samples. Therefore, the history of exposure and use relies on what the patients thought that they purchased, or the clinical syndrome in the absence of a more likely alternative.

Complications of phenibut overdose, whether accidental or intentional as part of misuse include coma requiring admission to an Intensive Care Unit for advanced life support, and risk of withdrawal syndromes. Confirmed cases of phenibut poisoning have been reported in Australia.
Public websites in Australia contain mixed reviews regarding the effect of phenibut. Some postings advocate its use for the treatment of anxiety and sleep based on personal experience and recommendations. Others report experiencing marked withdrawal syndromes. There is much discussion and debate regarding what is the optimal dose.

Taken together, there is evidence of risk of harm from phenibut use and it is being used to treat medical conditions that are preferably treated by a medical practitioner. Further, there is no established therapeutic role for phenibut.

ASCEPT is grateful for the opportunity to provide input into the Consultation. Please do not hesitate to contact the ASCEPT Secretariat at [redacted] for any further information.

Yours sincerely on behalf of ASCEPT,

[redacted]

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