

Submission:

Proposed amendments to the Poisons Standard, July 2016 (Medicines)

1. Proposed amendment:

PIPER METHYSTICUM (KAVA)	<p>Proposal to amend part a) of the existing Schedule 4 entry to include the following:</p> <ul style="list-style-type: none">• iii) the amount of dried whole or peeled rhizome in the unit dose of powder does not exceed 3 g; and, where containing more than 25 mg of kavalactones per dose, compliant with the requirements of the Required Advisory Statements for Medicine Labels; and is packaged with a dose controlled measuring device (Scoop); and is limited to a maximum quantity of 200g of powder per package;• or• iv) the liquid form contains 125 mg or less of kavalactones per unit dose of liquid. and, where containing more than 25 mg of kavalactones per dose, compliant with the requirements of the Required Advisory Statements for Medicine Labels; and is packaged in a single serve packaging. <p>It is also proposed that there is the addition of the mandatory warning statement "Do not exceed recommended daily dose" to be added to all Kava packaging.</p>
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Support for amendment:

The Happy Herb Company supports this amendment on the basis that Kava is a plant with a very long established precedent of use, well-researched toxicity, low relative potential for abuse, and significant demonstrated positive benefits.

Kava causes muscle relaxation, pleasant mood and social behaviour. It is used medicinally for anxiety, insomnia, urinary tract infections and pain, including arthritic pain. Current research shows promise for its use for attention deficit-hyperactivity disorder (ADHD), epilepsy, psychosis, depression, migraines and other headaches, chronic fatigue syndrome (CFS), common cold and other respiratory tract infections, tuberculosis, muscle pain, and cancer prevention.

2. Proposed amendment:

N,N-DIMETHYLTRYPTAMINE	Proposal to amend the entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. The quantity of DMT found per serving of the tea is approximately 0.25 mg/mL.
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Background:

DMT is a tryptamine that is produced endogenously in the brains of humans and other mammals and is also present in a wide variety of plant species. It is the primary psychoactive component of *ayahuasca*, a plant-based brew that - in keeping with global historical context - has been used in ceremonial settings for thousands of years by a wide range of independent Amazonian cultures. The typical intention of such usage is the healing of physical, mental, emotional and spiritual ailments. In recent decades use of the tea has begun to spread outside South America. It is widely purported to be effective in the treatment of addiction, severe emotional distress, depression, and a number of other conditions. There are legal precedents from court rulings in the USA and EU upholding citizens' rights to the sacramental use of DMT decoctions.

Brief summary of research relating to the risks/benefits, toxicity, and potential for abuse of brews containing DMT:

- A 1996 paper in the Journal of Nervous & Mental Disease surveyed a group of 15 regular ayahuasca users in Brazil and found that 11 out of the 15 participants had a history of moderate to severe alcohol use; 5 reported episodes of associated violent behaviour and a diagnosis of alcohol abuse disorder prior to their use of ayahuasca; 4 subjects also reported previous use of other drugs of abuse including cocaine and amphetamines; 2 subjects had past major depressive disorders; and 3 had past phobic anxiety disorders. The authors found that at the time of the assessment none of the subjects had a current psychiatric diagnosis using the CIDI. **According to the authors, the subjects' problems were resolved as a consequence of their regular ritual use of ayahuasca.**
Grob CS, McKenna DJ, Callaway JC, Brito GS, Neves ES et al. Human psychopharmacology of hoasca, a plant hallucinogen used in ritual context in Brazil. J Nerv Ment Dis. 1996; 184(2):86-94.
- An entry in the 2005 Journal of Psychoactive Drugs found that first time ayahuasca users exhibited a **“remarkable reduction of minor psychiatric symptoms”** and **“calmer, more assertive and vivacious behaviours”**.
Riba, J. y Barbanoj, M.J. “Bringing ayahuasca to the clinical research laboratory”, Journal of Psychoactive Drugs. 2005; 37(2): 219-30.
- A 2007 study noted that “Separate animal studies of the median lethal dose of DMT and of several harmala alkaloids indicated that a lethal dose of these substances in humans is probably greater than 20 times the typical ceremonial dose.” and concluded that **“a decoction of DMT and harmala alkaloids used in religious ceremonies has a safety margin comparable to codeine, mescaline or methadone. The dependence potential of oral DMT and the risk of sustained psychological disturbance are minimal.”**
Gable RS. Risk assessment of ritual use of oral dimethyltryptamine (DMT) and harmala alkaloids. Addiction. 2007;102(1):24-34.
- The Journal of Ethnopharmacology published a paper in 2007 which found that ayahuasca had a **significant effect in relieving feelings of anxiety, hopelessness and panic** in a group of study participants.
Santos RG, Landeira-Fernandez J, Strassman RJ, Motta V, Cruz AP. Effects of ayahuasca on

psychometric measures of anxiety, panic-like and hopelessness in Santo Daime members. J Ethnopharmacol. 2007. 112(3):507-13

- The Medical Science Monitor in 2008 studied the long-term health and safety of 32 regular ayahuasca users in Oregon (USA). The study found that while most of them had shown some past psychiatric disorder or some drug or alcohol abuse disorder, at the time of the assessment all had low anxiety and no reactivation of addictions, only two of them reported an active psychiatric disorder. Again, the participation in the ayahuasca rituals is thought to be responsible of the reported benefits. **The study states that “There simply is no evidence from within the data collected to assert that there are concerning harms.”**
Halpern JH, Sherwood AR, Passie T, Blackwell KC, Rutenber AJ. Evidence of health and safety in American members of a religion who use a hallucinogenic sacrament. Med Sci Monit. 2008; 14(8):SR15-22.
- A study from the Journal of Psychoactive Drugs in 2009 looked at the effects of ayahuasca over six months on people who hadn't previously drank the tea. The results found **no adverse impact on quality of life or psychiatric symptoms. Regular users did score higher, however, on tests of emotional and social functioning.**
Barbosa PC, Cazorla IM, Giglio JS, Strassman R. A six-month prospective evaluation of personality traits, psychiatric symptoms and quality of life in ayahuasca-naïve subjects. J Psychoactive Drugs. 2009. 41(3):205-12.
- In a 2010 study designed specifically to assess clinical efficacy of ayahuasca involving 3 female participants with a clinical diagnosis of recurring depressive disorder and current mild/severe depressive episode without psychotic symptoms, subjects received an oral dose of 3ml/kg of ayahuasca. **After a single ayahuasca dose, depressive symptoms were significantly decreased from 40 minutes after intake until day 14, when symptoms began to reach baseline levels.**
Lima F, Ribero L, Machado JP, Porfirio J, Quevedo J, et al. The therapeutic potential of harmine and ayahuasca in depression: Evidence from exploratory animal and human studies. In: R. dos Santos (Ed.): The Ethnopharmacology of Ayahuasca. 2010. Kerala, India, Research Network. Pp: 75-85.
- An article in Drug and Alcohol Dependence in 2010 assessed the addiction potential of ayahuasca. **The results did not suggest any addictive properties of the brew, but rather that it helped people conquer other addictions.**
Fábregas JM, González D, Fondevila S, Cutchet M, Fernández X, et al. Assessment of addiction severity among ritual users of ayahuasca. Drug Alcohol Depend. 2010. 111(3):257-61.

Suggested improvements to the amendment:

Although changes to the SUSMP will be insufficient to effectively alter legislation pertaining to the use of ayahuasca/DMT in Australia, any small move in this direction is welcome. In terms of scheduling, to begin to approach a basic level of efficacy it would be preferable if this amendment was expanded to:

- *alter the scheduling of harmala alkaloids (currently S9) which are an absolutely vital component of the ayahuasca brew;*
- *provide for the cultivation/possession/distribution of plants containing DMT and harmala alkaloids;*
- *make any provisions possible for the legal importation of these substances/plants;*
- *define, replace, or supplement the term 'religious use'.*

Support for the amendment:

The Happy Herb Company broadly supports this amendment on the basis that this is a substance with low toxicity, low potential for abuse, and significant demonstrated positive benefits. All of this is in addition to the pertinent issue of human rights/religious freedoms. In short, we believe that people's right to access this extremely useful medicine should be upheld.

About the Happy Herb Company

"Promoting the appreciation, information, benefits, culture, use, and availability of all natural plants and herbs."

Happy Herb Shops can be found all around the country, with roughly 40 locations across Australia and the USA. We stock a wide range of herbs, herbal extracts and other natural products to enhance health and well-being.

Many of our shops also offer consultations with qualified herbalists and naturopaths. As a not-only-for-profit business, the company is proud to donate 10% of all its profits towards social enterprise ventures to further support local and international communities.

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