

Public Consultation on the Proposed Amendments to the Poisons Standard

Notice under subsections 42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations)

The delegate of the Secretary to the Department of Health publishes herein all valid public submissions made in response to the delegate's interim decision. These submissions were considered by the medicines scheduling delegate when making their final decision.

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had their confidential information removed.

Materials claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out the Chapter 6 of the Scheduling Policy Framework for Medicines and Chemicals (SPF, 2015), issued by the Australian Health Ministers' Advisory Council. The SPF is accessible at <https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals>.

[REDACTED]

16 September 2016

Medicines Scheduling Secretariat,
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden
ACT 2606

Dear Secretariat,

Ulipristal Acetate (UPA): Application for rescheduling from Schedule 4 to Schedule 3

With regard to our previous submission supporting the application by [REDACTED]
[REDACTED] for the rescheduling of UPA from a Schedule 4 medication to Schedule 3, [REDACTED]
[REDACTED] would like to provide the following information.

[REDACTED]

Since initial TGA approval of UPA as a Schedule 4 medication, [REDACTED] clinicians have reported that there has been an increase in uptake and demand for UPA in comparison to Levonorgestrel emergency contraception (LNG-EC) with no reported incidents of adverse or safety concerns in any of [REDACTED] clinics. This is consistent with findings reported overseas.ⁱ

Clinical indications for preferentially prescribing UPA include its increased efficacy up to 24 hours in comparison to LNG-EC and the extended effectiveness of UPA for up to 120 hours.ⁱⁱ It is believed the rescheduling of UPA to Schedule 3 would facilitate access to more effective emergency contraception for women who meet these criteria and are not on hormonal contraception.

UPA has approval for use as emergency contraception in over 90 countries world-wide with an estimated 9 million patient exposures. It is currently available without a doctor's prescription in over 25 European countries which supports the premise that UPA can be easily, correctly and safely used by a consumer without direct involvement of a medical practitioner. Importantly, to date, non-prescription use of emergency contraception has not shown an increase in the frequency of unprotected intercourseⁱⁱⁱ or an increase in the sexual risk taking behaviour of teenagers.^{iv}

[REDACTED] therefore strongly supports the application for the rescheduling of UPA from Schedule 4 to Schedule 3 as it will facilitate access to highly effective emergency

[REDACTED]

[REDACTED]

contraception which will ultimately decrease the number of unplanned and unwanted pregnancies in Australia.

[REDACTED]


[REDACTED]

ⁱ Royal College of Obstetricians and Gynaecologists: Faculty of Sexual and Reproductive Health. CEU Statement on Emergency Contraception. (updated January 2012)

ⁱⁱ Glasier et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *The Lancet* 2010;375:555-562

ⁱⁱⁱ Moreau C, Bajos N, Trussell J. The impact of pharmacy access to emergency contraceptive pills in France. *Contraception*. 2006;73:602-608.

^{iv} Raine TR, Riocciotti N, Sokoloff A, Brown BA, Hummel A, Harper CC. An over-the-counter simulation study of a single-tablet emergency contraceptive in young females. *Obstet Gynecol*. 2012;119:772-9.



21 September 2016

The Secretary
Communications and Secretariat
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Delegates' Interim Decisions - Hexachlorophene

There is a problem with the proposed change to the entry in Schedule 2 for Hexachlorophene. Cosmetic preparations containing 0.75% or less of hexachlorophene would be both exempt under clause (a) and Schedule 6 poisons under clause (c). I suggest that the entry be reworded to read as follows:

HEXACHLOROPHENE in preparations for human use containing 3 per cent or less of hexachlorophene **except:**

- (a) in preparations for use on infants, as specified in Schedule 4;
or
- (b) in preparations for cosmetic use, as specified in Schedule 6;
or
- (c) in other preparations containing 0.75 per cent or less of hexachlorophene.

Yours sincerely





20 September 2016

Medicines Scheduling Secretariat,
Medicines Scheduling
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606

To whom it may concern,



██████████ welcomes the opportunity to further support the rescheduling of ulipristal acetate (UPA) - ██████████ for emergency contraception (EC) by ██████████ from Schedule 4 to Schedule 3.

In our previous submission on April 29th 2016, we outlined the history of emergency contraception in Australia and the issues that occurred when it needed to be obtained with a doctor's prescription. The introduction of a levonorgestrel (LNG) EC product registered for use in Australia and soon after, its rescheduling to Schedule 3 in January 2004, was an important decision in significantly improving timely access to emergency contraception for Australian women. Pharmacists are well placed to provide women with an appropriate consultation, comprehensive information about the medication and when appropriate, referral to other services. Specific guidelines are provided by their professional body, the ██████████. We note the comment from the Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS (July 2016), that, as stated in the PI, breast feeding mothers need to express and discard breast milk for 7 days following the use of UPA. We are confident that the ██████████ will ensure that pharmacists provide correct information about this aspect (and all others) of UPA provision, and where appropriate, will refer breast feeding women to appropriate support following use of UPA as part of a comprehensive consultation with women.

As noted in our previous submission, the literature supports the efficacy and tolerance of UPA (Trussell et al 2016; Brache et al 2013; Fine et al 2010; Glasier et al 2010; Creinin et al 2006). We reiterate that the requirement for UPA EC to be obtained on prescription has the potential to both restrict its use and act as a barrier to a safe and effective method of contraception for women following unprotected sexual intercourse, contraceptive failure or sexual assault. Although it is efficacious up to 120 hours, the earlier it is taken, the higher the efficacy (PI 2015). Provision of UPA EC in addition to LNG EC in pharmacies will promote easier access for women of all ages and will remove potential confusion for the community because there will be consistent provision of both methods of oral EC.

██████ has member organisations in each state and we are aware that there has been an increase in enquiries and uptake of UPA with no reported incidents or safety concerns. UPA is now available in 90 countries and is a non-prescription item in 25 countries. In three countries, UPA is available in pharmacies on the open shelves. The widespread provision of UPA in pharmacies throughout the world, supports the position to reschedule UPA from S4 to S3.

Conclusion

The timely and easily accessible provision of all types of emergency contraception to prevent an unwanted pregnancy requires removal of as many barriers as possible. Rescheduling of UPA from Schedule 4 to Schedule 3 in Australia is an important strategy to assist women in this situation. As described in this and our previous submission, UPA is a safe and effective EC and is already available in pharmacies in 25 countries. The [REDACTED] strongly supports the rescheduling of this medication to reduce the number of unintended pregnancies and abortions in Australia.

Yours Sincerely

REFERENCES

- Brache V, Cochoon L, Deniaud D, Croxatto, HB 2013 Ulipristal acetate prevents ovulation more effectively than levonorgestrel: analysis of pooled data from three randomized trials of emergency contraception regimens. *Contraception* 88: 611-118
- Creinin MD, Schlaff W, Archer DF, Wan L, Frezieres R, Thomas M, Rosenberg M, Higgins J 2006 Progesterone receptor modulator for emergency contraception: a randomized controlled trial. *Obstet Gynecol.* 108:1089-97
- Fine P, Mathé H, Ginde S, Cullins V, Morfesis J, Gainer E 2010 Ulipristal acetate taken 48-120 hours after intercourse for emergency contraception. *Obstet Gynecol.* 115:257-63
- Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, Sogor L, Blithe DL, Scherrer B, Mathe H, Jaspart A, Ulmann A, Gainer E 2010 Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *Lancet* 375:555-62
- Pharmaceutical Society of Australia 2015 Guidance for provision of a Pharmacist Only medicine Levonorgestrel. Approved indication: emergency contraception. Canberra
- Product Information EllaOne 2015 Accessed online www.tga.gov.au/sites/default/files/auspar-ulipristal-acetate-150904-pi.pdf
- Therapeutic Goods Administration (TGA) 2015 Public Summary - EllaOne ulipristal acetate 30 mg tablet blister pack. Accessed online [www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=219535&agid=\(PrintDetailsPublic\)&actionid=1](http://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=219535&agid=(PrintDetailsPublic)&actionid=1)
- Trussell J, Raymond EG, Cleland, K 2016 Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy. Accessed online www.ec.princeton.edu/questions/ec-review.pdf

Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
Department of Health
By email: medicines.scheduling@tga.gov.au

26 September 2016

Dear Committee,

Re: Additional 2nd round comment regarding the proposal to amend the existing Schedule 4 entry for ULIPRISTAL and create a new Schedule 3 entry to allow for emergency post-coital contraceptive use

I am writing on behalf of [REDACTED] regarding the above topic as it related to creating a new Schedule 3 entry for Ulipristal.

[REDACTED] understands that a new emergency contraceptive, which uses the active ingredient Ulipristal acetate, has recently been made available in Australia. Our understanding is that this new emergency contraceptive has a similar safety profile to levonorgestrel and has been shown to be more effective¹.

Given the similar safety profile to levonorgestrel, [REDACTED] considers that Ulipristal acetate for emergency contraception should be advertised directly to consumers, who will be primarily women. Direct advertising is needed given the findings of Hobbs et al in 2011 which showed only 43.4% of women surveyed knew emergency contraception was available through pharmacies.² Direct consumer advertising would enhance reach and access for women in a timely manner. A study published in Health Education Journal evaluated the effectiveness of a UK radio advertising campaign, concluding the campaign was worthwhile and the need for emergency contraception advertising to be clear and unambiguous.³

The [REDACTED] supports:

- the re-scheduling of Ulipristal acetate as a Schedule 3 medicine
- the direct advertising of Ulipristal acetate to consumers, and
- the advertising to be clear and unambiguous.

[REDACTED] you would like further information.

¹ Glasier *et al.*, Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *Lancet*. 2010: 375.

² Hobbs MK *et al.* Pharmacy access to the emergency contraceptive pill: a national survey of a random sample of Australian women. *Contraception* 2011;83:151-8

³ Hall C, Milner P. Advertising emergency contraception using local radio: an evaluation. *Health Education Journal* 1996;55(2):165-174

28 September 2016

Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
Department of Health
By email: medicines.scheduling@tga.gov.au

Dear Committee,

Re: Additional 2nd round comment regarding the proposal to amend the existing Schedule 4 entry for ULIPRISTAL and create a new Schedule 3 entry to allow for emergency post-coital contraceptive use

In addition to our submission of 2 May 2016 regarding the above proposal I write to include further information.

[REDACTED] understands that a new emergency contraceptive, which uses the active ingredient Ulipristal acetate, has recently been made available in Australia. Our understanding is that this new emergency contraceptive has a similar safety profile to levonorgestrel and has been shown to be more effective ¹.

Given the similar safety profile to levonorgestrel, [REDACTED] considers that Ulipristal acetate for emergency contraception should be advertised directly to consumers, who will be primarily women. Direct advertising is needed given the findings of Hobbs et al in 2011 which showed only 43.4% of women surveyed knew emergency contraception was available through pharmacies.² Direct consumer advertising would enhance reach and access for women in a timely manner. A study published in Health Education Journal evaluated the effectiveness of a UK radio advertising campaign, concluding the campaign was worthwhile and the need for emergency contraception advertising to be clear and unambiguous.³

¹ Glasier *et al.*, Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *Lancet*. 2010; 375.

² Hobbs MK *et al.* Pharmacy access to the emergency contraceptive pill: a national survey of a random sample of Australian women. *Contraception* 2011;83:151-8

³ Hall C, Milner P. Advertising emergency contraception using local radio: an evaluation. *Health Education Journal* 1996;55(2):165-174

[REDACTED] supports:

- the re-scheduling of Ulipristal acetate as a Schedule 3 medicine
- the direct advertising of Ulipristal acetate to consumers, and
- the advertising to be clear and unambiguous.

Please do not hesitate to contact me if you would like further information.

Yours sincerely,

[REDACTED]

[REDACTED]

Medicines Scheduling Secretariat,
Medicines Scheduling
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden
ACT 2606
Australia

September 21st, 2016

To whom it may concern,

[REDACTED]
[REDACTED] welcomes the opportunity to further support the rescheduling of ulipristal acetate (UPA) -
[REDACTED] for emergency contraception (EC) by [REDACTED] from Schedule 4 to
Schedule 3.

Access to emergency contraception

As noted in our previous submission, timely access to emergency contraception is critical. Australian women have had improved access to LNG emergency contraception since 2004. Women are aware that the main point of access to EC is from pharmacies with a pharmacist consultation and without the need to obtain a doctor's prescription. Rescheduling of UPA to Schedule 3 will both provide easier access to emergency contraception and will remove potential confusion for the community because there will be consistent provision of both methods of oral EC. We reiterate that pharmacists provide a comprehensive consultation when providing EC and are guided and supported by the Pharmaceutical Society of Australia (PSA 2015).

UPA - safety and efficacy

We again stress that UPA is an effective method of emergency contraception. Additionally, it is more effective than LNG and is effective for up to 120 hours after unprotected sexual intercourse providing more leeway than LNG EC which is licensed for up to 72 hours. As with LNG EC, UPA should be taken as soon as possible following unprotected sexual intercourse and is more effective if taken in the first 24 hours (PI 2015). Many women are unaware that they are at the most fertile time of their menstrual cycle (Lundsbert et al 2014), so early use of EC will improve the chance of preventing or disrupting ovulation and thus a possibility for pregnancy. Removing the need for a doctor's prescription will facilitate this early use. The safety, efficacy and tolerance profile of UPA has been extensively reported (Trussell et al 2016; Brache et al 2013; Fine et al 2010; Glasier et al 2010; Creinin et al 2006).

UPA – international availability

UPA has been available in Europe and other countries since 2009 and its introduction in Australia as an additional EC option for Australian women (TGA 2015) is welcomed. It is currently available in 90 countries, without prescription in 25 countries and in 3 of those countries (Norway, Sweden and Luxembourg) is available on the open shelves in pharmacies. This availability attests to the safety profile of UPA.

Conclusion

As stated in our previous submission, [REDACTED] strongly supports the rescheduling of UPA to Schedule 3, thus removing the barrier of obtaining UPA with a doctor's prescription and delaying commencement of treatment. This can only serve to contribute to improved and timely access to UPA. The proposed rescheduling of UPA to Schedule 3 is one of the strategies to assist women in controlling their fertility and reducing the number of unintended pregnancies and abortions in Australia as well as a bridge to ongoing and more effective contraception.

For further information, please contact:-

[REDACTED]

[REDACTED]

[REDACTED]

REFERENCES

- Brache V, Cochon L, Deniaud D, Croxatto, HB 2013 Ulipristal acetate prevents ovulation more effectively than levonorgestrel: analysis of pooled data from three randomized trials of emergency contraception regimens. *Contraception* 88: 611-118
- Creinin MD, Schlaff W, Archer DF, Wan L, Frezieres R, Thomas M, Rosenberg M, Higgins J 2006 Progesterone receptor modulator for emergency contraception: a randomized controlled trial. *Obstet Gynecol.* 108:1089-97
- Fine P, Mathé H, Ginde S, Cullins V, Morfesis J, Gainer E 2010 Ulipristal acetate taken 48-120 hours after intercourse for emergency contraception. *Obstet Gynecol.* 115:257-63
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- Jatlaoui TC, Riley H, Curtis KM 2016 Safety data for levonorgestrel, ulipristal acetate and Yuzpe regimens for emergency contraception. *Contraception* 93:93-212
- Lundsberg LS, Pal L, Garipey AM, Xu X, Chu MC, Illuzzi JL 2014 Knowledge, attitudes, and practices regarding conception and fertility: A population-based survey among reproductive-age United States women. *Fertil Steril.* 101:767–774
- Pharmaceutical Society of Australia 2015 Guidance for provision of a Pharmacist Only medicine Levonorgestrel. Approved indication: emergency contraception. Canberra
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- Therapeutic Goods Administration (TGA) 2015 Public Summary - EllaOne ulipristal acetate 30 mg tablet blister pack. Accessed online [www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=219535&agid=\(PrintDetailsPublic\)&actionid=1](http://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=219535&agid=(PrintDetailsPublic)&actionid=1)
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22 September 2016

Medical Scheduling Secretariat
Medicines Scheduling Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606

Dear Secretariat,

Earlier this year, we made a submission in support of the re-scheduling of ulipristal acetate (UPA [REDACTED]) from a Schedule 4 prescribed medication to Schedule 3 status.

We welcome the opportunity to re-iterate our support in this second-round submission, in light of our clinical experience in prescribing UPA since it became available in April 2016.

Background

Ulipristal acetate (UPA) 30mgs has been available as an emergency contraceptive (EC) in Australia since April 2016 under the tradename [REDACTED]

UPA is a selective progesterone receptor modulator which works as an emergency contraceptive by preventing or delaying ovulation until five days after intercourse when sperm are no longer viable in the female genital tract.

UPA is currently available only by private prescription for use after unprotected intercourse, contraceptive failure or sexual assault.

Clinical experience of UPA is extensive, with UPA available in 90 countries worldwide since 2009. UPA has been made available as a non-prescription medication in 25 countries including the UK and, most recently, Switzerland.

Public health benefits of timely access to UPA

Prevention of unintended pregnancy is a significant public health issue affecting women of all reproductive ages, including teenagers. Unintended pregnancy can result from failed contraception such as condom breakage or missed contraceptive pills, as well as non-use of

contraception. UPA taken soon after unprotected intercourse is proven to prevent unintended pregnancy.

██████████ supports the rescheduling of UPA ██████████ from a Schedule 4 (S4) prescribed medication to a Schedule 3 (S3) medication which would be available at pharmacies without a prescription.

UPA has a well-demonstrated safety and efficacy profile and rescheduling would further promote its timely and easy access, supporting improved public health outcomes.

The 1.5mg levonorgestrel emergency contraceptive pill (LNG-ECP) has been included in Schedule 3 since 2004 with no evidence of harm at an individual or community level.

UPA has a similar safety profile but superior effectiveness to LNG-ECP.

A meta-analysis¹ has shown that UPA is significantly more effective than LNG-ECP at preventing pregnancies if taken within 24, 72 and 120 hours of unprotected intercourse.

UPA is licensed for use up to 120 hours after unprotected intercourse with proven effectiveness on the 4th and 5th day while LNG-ECP is only licensed for 72 hours with a loss of effectiveness on day 5. Administration of UPA within the first 24 hours is associated with greater effectiveness which makes timely access essential.

The safety of UPA is well established and it has few contraindications or precautions. There is no evidence to suggest that UPA taken inadvertently during pregnancy results in harm to either the pregnancy or the fetus.

Making UPA available through pharmacy settings, without the need to see a doctor for a prescription, allows women more autonomy over their reproductive health outcomes and supports improved and accessible public health outcomes, particularly in rural and regional communities.

Community pharmacists have over a decade of experience in the provision of emergency contraception through the existing LNG-ECP product and the provision of UPA will involve an extension of this service. Pharmacists will be supported by the provision of comprehensive information and training as well as evidence-based checklists so that they can fulfil their professional duty to provide professional and accessible advice to women. This will ensure that UPA is used safely and effectively and that women are provided with information about effective methods of ongoing contraception.

Experience of UPA in the ██████████ setting since April 2016

Since UPA became available in April 2016, ██████████ doctors have provided prescriptions to women requiring emergency contraception through our clinics and as well as information about UPA to clients using our confidential telephone and email service, ██████████

We have also provided expert advice and information about UPA to other clinical services, including sexual assault services. There have been no medical concerns raised about UPA during this time. However, concerns have been raised about the ability for women to access UPA in a timely manner given the current requirement for women to first seek a doctor's prescription prior to purchasing UPA at a pharmacy. This experience supports our

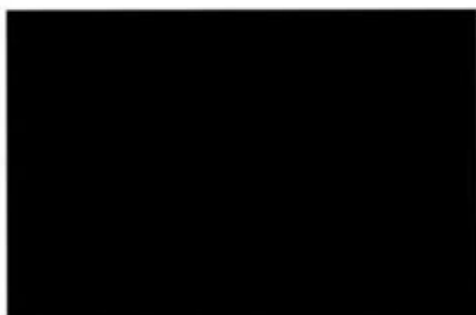
submission for the rescheduling of UPA from S4 to S3 status in order to improve access and maximise its public health benefit.

Conclusion

██████████ supports timely and easily accessible provision of all types of ECP, including UPA, to prevent unintended pregnancy and supports pharmacy access without the requirement of a doctor's prescription.

Removing this additional barrier to timely access for this highly effective and safe method of emergency contraception has already occurred in many countries and the public health benefits will only be realised in Australia if UPA is made available to women through their local pharmacy.

For further information, please contact:



¹Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, Sogor L, Blithe DL, Scherrer B, Mathe H, Jaspart A, Ulmann A, Gainer E, 2010 Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis, *Lancet* 375:555-62



Second Submission to the Therapeutic Goods Administration,
September 2016

Ulipristal: To amend the existing Schedule 4 entry and create a new
Schedule 3 entry to allow for emergency post-coital contraceptive

About [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

It is estimated that almost half of all pregnancies in Australia are unplannedⁱ. Unplanned pregnancy can occur for many reasons and under various circumstances. The reality is that contraception can fail, couples get carried away and some women may not be in a position to negotiate contraceptive use, due to the effects of alcohol or other drugs, lack of power in relationship decision-making, or being forced or coerced into having sex. For these women and couples emergency contraception is a viable option to prevent an unplanned pregnancy post unprotected sex.

Submission statement

As stated in our previous submission, [REDACTED] is supportive of measures to increase women's access to more effective contraception methods, including ulipristal, to reduce the number of unplanned pregnancies in Australia.

Clinical and biological evidence demonstrates that ulipristal is more effective than levonorgestrel, especially when taken within the first 24 hours after UPSI, at the time when the vast majority of women ask for EC. In addition, it is effective within 5 days (120 hours) of UPSI compared to 3 days (72 hours) for levonorgestrel.ⁱⁱ

Many barriers exist to contraceptive access for some women in Australia, and addressing these barriers is essential if women are to have full control over their fertility. As ulipristal is most effective if taken within 24 hours of unprotected sex, the removal of the requirement to obtain a

prescription for ulipristal is imperative for more women to benefit from this more effective emergency contraceptive method.

The requirement of a doctor prescription is not necessary as is evidenced in many European countries and only places an additional barrier to women's access. In addition the Australian experience with levonorgestrel demonstrates the advantages for women of over the counter pharmacy access to emergency contraception.

██████████ are very supportive of the re-scheduling of ulipristal acetate for emergency contraception to become a pharmacy medicine (Schedule 3) by the TGA.

Therefore, we welcome the TGA's interim verdict recommendation to re-schedule UPA EC to become a Schedule 3 medicine, with an effective date of 1st of February 2017. We urge the TGA to make this their final recommendation and bring Australia in line with many other countries internationally where ulipristal acetate is available without a doctor's prescription. ⁱⁱⁱ

ⁱ D Mazza, C Harrison, A Taft, B Brijnath, H Britt, M Hobbs, K Stewart, S Hussainy 'Current contraceptive management in Australian general practice: an analysis of BEACH data' Medical Journal of Australia 2012; 197 (2): 110-114. Available online at <https://www.mja.com.au/journal/2012/197/2/current-contraceptive-management-australian-general-practice-analysis-beach-data>.

ⁱⁱ Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis
Anna F Glasier, Sharon T Cameron, Paul M Fine, Susan J S Logan, William Casale, Jennifer Van Horn, Laszlo Sogor, Diana L Blithe, Bruno Scherrer, Henri Mathe, Amelie Jaspart, Andre Ulmann, Erin Gainer

ⁱⁱⁱ MS Health data on file. August 2016.

[REDACTED]

29 September 2016

Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
Medicines.Scheduling@tga.gov.au

Your Ref
[REDACTED]

Contact
[REDACTED]

Partner
[REDACTED]

Dear Sir / Madam

Interim decision regarding N,N-Dimethyltryptamine ("DMT") dated
15 September 2016 ("Interim Decision")

We have recently received instructions to act for [REDACTED]

Response to the Interim Decision

We note that the Interim Decision invites a response by today. Please find enclosed the [REDACTED] responsive submission.

Materials referred to in the Interim Decision

We note that the Interim Decision refers to:

- (a) the advice of the National Drugs and Poisons Schedule Committee received in June 2010; and
- (b) the advice of the Australian Committee on Medicines Scheduling received in July 2016.

We are instructed to request copies of the full reports or advices, if any.

We also note that the Interim Decision refers to:

- (a) "*international evidence*" in relation to the likelihood that levels of DMT of 0.25mg/mL would be exceeded; and
- (b) reports of the "*potential for abuse*".

We are instructed to request copies of the "*international evidence*" and "*reports*" considered by the ACMS and/or the delegate.



Please acknowledge receipt and confirm that copies of the materials requested above will be provided prior to the making of a final decision.

Yours faithfully

[Redacted signature]

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**Applicant's submission in relation to Delegate's interim decision regarding
N,N-Dimethyltryptamine ("DMT") dated 15 September 2016 ("Interim
Decision")**

1. The applicant (█████) sought an amendment to the Poisons Standard to permit the oral use in liquid form of N,N-dimethyltryptamine (DMT) where the concentration of naturally occurring DMT is 0.25mg/mL or less.
2. The delegate made an interim decision not to make the proposed amendment to the Poisons Standard.
3. This submission is made in response to the invitation to under reg 42ZCZP of the *Therapeutic Goods Regulations 1990* (the **Regulations**), and sets out matters that are relevant to the delegate's interim decision for the purpose of the Secretary's reconsideration of that decision under reg 42ZCZQ of the Regulations.
4. For the reasons summarised below, █████ submits that the Secretary should (pursuant to reg 42ZCZR of the Regulations) set aside the interim decision and substitute a decision to amend the Poisons Standard in the terms sought by █████ in its application dated 1 April 2015. The Secretary should then proceed to publish the final decision and make the amendment pursuant to reg 42ZCZS(b) of the Regulations.
5. The interim decision is largely based on the ACMS advice and reasons. █████ has not been provided with any report or documents prepared by the ACMS. In so far as the reasons for the ACMS advice is listed in point form by the delegate, █████ makes the following submissions in response.

- (a) *"The proposed use of naturally occurring DMT at low concentrations is for religious purposes as an entheogen. However, managing safety risks within this context is not clear;"*

The management of safety risks within the context of the proposed use for religious purposes is explained in detail in the original application. As noted in the overview, █████ has established clear safeguards to prevent any misuse and to limit any perceived risk to members who consume the tea. The safeguards are outlined at paragraphs 21 to 43 of

the application and the attachments referred to in the footnotes to those paragraphs.

- (b) *“Toxicity – the evidence is not clear for low doses. At high concentrations DMT has been reported to have marked psychotropic responses as well as common physical effects such as diarrhoea and vomiting;”*

The evidence in relation to toxicity and safety of Hoasca containing DMT at low doses is summarised in paragraphs 12 to 20 of the application and the attachments referred to in the footnotes to those paragraphs.

The ACMS advice also refers to toxicity of DMT at high concentrations. The proposed amendment does not permit use of DMT at high concentrations. Toxicity at high concentrations of a particular substance does not necessarily inform, or correlate with, toxicity at low concentrations. Many substances which can be safely consumed at low levels may be toxic at high concentrations (including, by way of example, caffeine). The delegate does not refer to evidence which permits any conclusion about the toxicity of DMT at low doses to be reached from evidence about its toxicity at high concentrations.

- (c) *“There is a lack of safety data regarding consumption of low doses of naturally occurring DMT at concentrations of than 0.25mg/mL used in a religious context. It is unlikely that psychoactive effects occur with DMT in the absence of harmaline alkaloids of which concentrations probably need to be approximately 2%;*”

Safety data regarding the consumption of low doses of naturally occurring DMT used in a religious context is summarised at paragraphs 3 to 20 of the application and the attachments referred to in the footnotes to those paragraphs. As appears to have been accepted by the ACMS, DMT at such doses is generally inactive when consumed orally, in the absence of the harmala alkaloids derived from the plants used to produce Hoasca. Those alkaloids are not themselves a scheduled substance, and their level of concentration is not directly

relevant to the safety of the consumption of naturally occurring DMT at concentrations less than 0.25mg/mL.

- (d) *“The potential interaction with other foods and common medicines (such as SSRI antidepressants) presents a significant risk that needs further investigation. To what extent that they are problematic at low concentrations is unclear. Further safety studies are required for low dose toxicity;”*

As set out in the application in the overview and at paragraph 23, all individuals who express an interest in attending a ritual are interviewed about their medical background, and further safeguards are set out at paragraphs 21 to 43. As set out above, safety data for Hoasca containing low doses of naturally occurring DMT is included in the application.

- (e) *“No information was provided on how brewing the tea would ensure levels of DMT would not exceed 0.25%. International evidence suggests levels of 0.25% would be exceeded;”*

The international evidence “suggesting” levels of 0.25% would be exceeded is not identified so as to enable the applicant to respond to it. The applicant is not seeking an amendment to the Poisons Standard so as to permit the oral use of naturally occurring DMT at concentration levels higher than 0.25 mg/mL (or 0.25%.) The tea which is proposed to be used for religious purposes has been tested and found to contain DMT of 0.25% as set out in paragraph 17 of the application. Proposed controls are set out at paragraph 42 of the application. There is no suggestion, nor any evidence, that the level of DMT in brewed tea cannot be tested.

- (f) *“Potential for abuse has been reported and is likely to be similar to other compounds such as mescaline, peyote etc. Risks of dependence are unknown when used at low concentrations;”*

No reports of abuse have been identified so as to enable the applicant to respond to apparent reported potential for abuse. There is no evidence that the potential for abuse is “likely to be similar to other

compounds” (nor has a full list of such compounds been identified due to the use of “etc”). Paragraphs 42 and 43 of the original application address the potential for abuse, including evidence from use in other countries in which Hoasca has been legalised. The evidence is that the continued use of low dose DMT is safe and without adverse effects, as set out in paragraphs 12 to 20 of the application.

- (g) *“It is unclear that the proposed use justifies the public health risks of this substance.”*

As set out at paragraphs 6-10 and 67 of the original application, the proposed use of Hoasca containing low doses of DMT is a necessary and essential part of the manifestation of the Centro Espirita Beneficente Uniao do Vegetal religion. The importance and necessity of the proposed use to the religion is not addressed in the decision. The public health risks are addressed at paragraphs 11, 18, 41-43 and 69-71 of the application. For the reasons explained in the application, the proposed use at low concentrations does not pose a threat to public health.

6. The summary of the ACMS Advice reasons does not refer to, and the interim decision did not consider, any of the matters identified in paragraphs 44 to 70 of the application.
7. The delegate stated that consideration had been given to public submissions received, but no public submissions are referred to under the heading “Delegate’s interim decision” and it does not appear that any of the matters raised in any of the public submissions have been addressed in the decision.
8. The delegate stated that consideration had been given to “other relevant information”, but no other information has been identified or made available to [REDACTED] and the delegate did not explain how any such information informed the interim decision. The applicant is therefore unable to respond to, or comment upon, this other information.
9. The delegate stated that consideration had been given to the Scheduling Policy Framework (SPF 2015) but did not identify how the SPF 2015 informed the delegate’s interim decision.

10. The delegate referred to a previous consideration of entheogenic substances by the National Drugs and Poisons Schedule Committee (NDPSC) in June 2010, which in turn considered the decision of the Federal Court in *Hanes v Human Rights and Equal Opportunity Commission* [2007] FCA 751, in which the applicant sought judicial review of a decision of the Human Rights and Equal Opportunity Commission not to investigate a complaint in relation to a scheduling decision regarding *Salvia divinorum*. The NDPSC stated that “the manifestation of one’s religion or belief may be subject to limitations prescribed by law and which are necessary to protect public health and safety”. However, the interim decision does not consider whether the refusal of the proposed use of DMT for religious purposes is necessary to protect public health and safety, nor make any finding to that effect.
11. More generally, it is not evident how the NDPSC’s consideration of the scheduling of entheogenic substances was taken into account by the delegate in reaching the interim decision. The June 2010 NDPSC did not consider ██████ proposed amendment to the Poisons Standard.
12. As is clear from the application, the proposed amendment is limited to *naturally occurring* DMT at low concentrations of 0.25mg/mL or less. As set out at paragraphs 3-5 and Attachment Q of the original application, neither the plant containing the DMT (in the present case, *Chacrona* or *Psychotria Viridis*) nor preparations made of that plant are controlled under the 1971 Convention on Psychotropic Substances. This is also true of other plants or preparations which contain naturally occurring DMT, such as *Acacia* and *Acacia* tea (traditionally used by some Aboriginal people for religious and cultural purposes).
13. ██████ submits that, for the reasons outlined in the application and the public submissions, refusal of the proposed amendment would limit the religious practice identified in the application, and such a limitation is not made necessary by reason of any identified risk to public health and safety. All of the evidence concerning the risks to public health and safety of the proposed use of DMT supports the making of the proposed amendment. Both the ACMS advice and the delegate’s reasons emphasise a perceived lack of knowledge or information, and instead appear to rely on (unidentified)

anecdotal reports in relation to safety risks and potential for abuse. [REDACTED] submits that there is sufficient evidence on which to find that the proposed use of Hoasca for religious purposes is safe, and that any perceived or possible risks can be appropriately managed in the context of the proposed use. If necessary, [REDACTED] remains prepared to work with the TGA in conjunction with the ACMS, the Department of Health and any other stakeholders to develop further guidelines in relation to the proposed use of Hoasca for religious purposes. In such circumstances, the refusal of the proposed amendment, so as to limit the religious freedom of the members of the applicant, cannot be regarded as necessary for the protection of public health and safety.

14. Accordingly, for the reasons set out above and in the application dated 1 April 2015, [REDACTED] submits that the interim decision should be set aside, and the Poisons Standard should be amended to permit the oral use in liquid form of DMT where the concentration of naturally occurring DMT is 0.25mg/mL or less.