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 March 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #20), the Advisory Committee on Chemicals Scheduling (ACCS #19), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #15), was made available on the TGA website on 22 December 2016 and 3 February 2017, closing on 10 February 2017 and 3 March 2017 respectively.

Public submissions received on or before these closing dates (10 February 2017 and 3 March 2017) are published here in accordance with regulation 42ZCZL of the Regulations. Also in accordance with 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 also 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 March 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #20), the Advisory Committee on Chemicals Scheduling (ACCS #19) and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #15) was made available on the TGA website on 17 May 2017 and 15 September 2017, closing on 31 May 2017 and 3 October 2017 respectively. Public submissions received on or before these closing dates will be published on the TGA website in accordance with regulation 42ZCZQ.

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.

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

Re: MS Health application for ulipristal acetate (ulipristal acetate) [redacted] to be included in Appendix H.

January 27th, 2017

To whom it may concern

[redacted] the leading reproductive and sexual health organisation in [redacted]. It provides clinical and education services to the [redacted] community.

[redacted] supports the application by Marie Stopes Health Pty Ltd to list ulipristal acetate (UPA) [redacted] on Appendix H.

Historically in Australia, no emergency contraceptive product has been included in Appendix H. Whilst many issues related to the access and availability of emergency contraception have been facilitated through the scheduling of levonorgestrel emergency contraception since 2004 and ulipristal acetate as of February 1st, 2017 as Schedule 3 medications, the missing part has always been the lack of advertising to the general public. A number of Australian studies have identified that overall knowledge about emergency contraception could be improved in Australia (Calabretto 2009; Hussainy et al 2009; Mazza et al 2009; Hobbs et al 2011).

Trussell et al (2016) cite several studies demonstrating the impact of modest and more extensive direct-to-consumer media campaigns in print, radio, television and outdoor venues in the USA in increasing knowledge about emergency contraception.

In Australia, inclusion on Appendix H should assist in uptake of EC generally, and will complement other sources of information and education about emergency contraception by family planning and related organisations in Australia through their printed and web-based materials and the education of health and education professionals. Direct to consumer marketing will not only promote UPA, but importantly it will also serve to raise awareness of emergency contraception more generally in the community. An increased uptake of emergency contraception has the potential to prevent unplanned pregnancies, contributing to the reduction of direct and indirect costs to the health care system (Trussell & Calabretto 2005).

We are confident that Marie Stopes Health have carefully considered each aspect and meet all of the criteria for the inclusion in Appendix H:-

Public health benefits
Likelihood that advertising will lead to inappropriate use
The wide regulatory system and advertising codes
The responsibility of pharmacists for supply
Whether advertising will result in the good being used for other indications
Available consumer medicine information
The level of patient education required for correct use
The desire of consumers to manage their own medication

The majority of countries where ulipristal acetate is available without prescription are able to advertise directly to the public. Making both levonorgestrel and ulipristal acetate Schedule 3 medications were important decisions in significantly improving timely access to emergency contraception for Australian women. The inclusion of ulipristal acetate in Appendix H will provide the next important strategy to assist in the uptake of emergency contraception to prevent unwanted pregnancies which will benefit both individual women and the community more generally.

For further information, please contact:-

[redacted]

Yours sincerely

[redacted]

REFERENCES

Calabretto H 2009 Emergency contraception - knowledge and attitudes in a group of Australian university students. *Australian and New Zealand Journal of Public Health*. 33(3): 234-239

Hobbs MK, Taft AJ, Amir, Stewart K, Shelley JM, Smith AM, Chapman CB, Hussainy SY 2011 Pharmacy access to the emergency contraceptive pill: a national survey of a random sample of Australian women *Contraception* 83: 151-158

Hussainy SY, Ghosh A, Taft A, Mazza D, Black KI, Clifford R, Gudka S, Mc Namara KP, Ryan K, Jackson JK 2015 Protocol for ACCESS: a qualitative study exploring barriers and facilitators to accessing the emergency contraceptive pill from community pharmacies in Australia. *BMJ Open* 2015; 5:e010009. www.dx.doi.org/10.1136/bmjopen-2015-010009

Mazza D, Harrison CM, Taft AJ, Britt HC, Hobbs M, Stewart K, Hussainy S, Brijnath BR. Emergency contraception in Australia: The desired source of information versus the actual source of information. *Medical Journal of Australia* 2014; 200(7):414-5

Trussell J, Calabretto H 2005 Cost savings from use of emergency contraceptive pills in Australia. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 45:308-311

Trussell J, Raymond EG, Cleland K 2016 Emergency Contraception: A last chance to prevent unintended pregnancy http://ec.princeton.edu/questions/ec-review.pdf

[redacted]

Submission to

Medicines Scheduling Therapeutic Goods Administration

Appendix H application promotion of [redacted]

February 2017

Public submission for an Appendix H application.

Medicines Scheduling Secretariat

Medicines Scheduling

Therapeutic Goods Administration

Department of Health, PO Box 100

Woden, ACT, 2606, Australia

Medicines.Scheduling@tga.gov.au

www.tga.gov.au

Electronic submissions are preferred, and should be sent to the medicines.scheduling@tga.gov.au website.

Introduction

The Australian Women's Health Network is an interested group in relation to the application to have [redacted] (ulipristal) added to the Appendix H registry which is currently before the Australian Committee on Medicine Scheduling (ACMS). We are pleased to have the opportunity to make a submission on the promotion of [redacted] (ulipristal) and the benefits of emergency contraception directly to women.

The Australian Women's Health Network (AWHN)

The Australian Women's Health Network (AWHN) provides a national voice for women's health issues, with woman centred analysis of health care models and research. AWHN adopts a social view of health within a health promotion framework, drawing on a variety of interventions with an aim to prevent women's illness, disease and injury, and to promote women's independence, health and wellbeing. Further information about the organisation and how to become a member can be found on the AWHN website.

AWHN submission

AWHN understands that it is currently illegal for any brand of emergency contraceptives to be advertised to women. We are of the strong view that:

- women should be able to easily access information on the different forms or brands of emergency contraception;
- this would improve awareness of contraception options;
- this would have a direct reproductive health benefit for women by enabling them to avoid unplanned pregnancies.

[redacted] is an emergency contraceptive pill with the active ingredient ulipristal acetate ('ulipristal'). [redacted] is indicated for emergency contraception ('EC') within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. As of 1st February 2017, [redacted] is available in Australia as a Schedule 3 medicine.

AWHN understands that MS Health has submitted an application to the Australian Committee on Medicine Scheduling (ACMS) to have [redacted] (ulipristal) added to the Appendix H registry. If successful this would enable the promotion of AWHN [redacted] (ulipristal) and the benefits of emergency contraception directly to women.

AWHN Sexual and Reproductive Health Position paper 2014 Page 18 states as follows:

> 'Emergency contraception (EC) is available over the counter through Australian pharmacies, but women's knowledge of EC is poor. Many believe it must be taken the morning after unprotected sex, whereas it remains effective for up to 120 hours (Hussainy, 2011). EC is not listed on the Pharmaceutical Benefits Scheme, resulting in decreased affordability. Furthermore, some pharmacists refuse to supply EC to women due to religious beliefs and the mistaken view that EC causes abortion. Currently some states and territories also

prohibit pharmacists supplying to women under 16 years of age. Increased awareness, affordability, and advance supply of EC, along with improved training of pharmacists and medical practitioners, have the potential to significantly lower unplanned pregnancy rates in Australia.

Action 15: It is recommended that education programs for pharmacists and other health practitioners be developed and implemented, along with a public awareness campaign concerning the use and effectiveness of emergency contraception.'

It is this public awareness that AWHN asserts would be assisted by having [redacted] (ulipristal) added to the Appendix H registry

There are public health benefits in raising women's knowledge of the availability, safety and effects of emergency contraception. Specific, targeted, responsible advertising that reinforces the important role of pharmacists has considerable potential to reverse this situation with a significant reduction in unplanned pregnancies and consequent abortions. This would have important direct and indirect benefits for public health and in avoiding the social and economic costs of abortions.

AWHN is of the view that the advertising of ulipristal is unlikely to lead to inappropriate patterns of medication use because we understand that:

- ulipristal will remain in Schedule 3 meaning a pharmacist must be personally involved in every sale;
- the pack contains a single tablet so the potential for inappropriate or incorrect use is very low; and
- all forms of advertising will emphasise the important role of pharmacists in advising women on the correct and appropriate use of [redacted]

AWHN Sexual and Reproductive Health Position paper 2014 outlined that knowledge of the availability, safety and effects of emergency contraception is poor among Australian women. Women do want to exercise more control over their own health, particularly in regards when and if they will bear a child. Effective use of emergency contraception, particularly knowledge of when it can be taken is important for women to understand. Responsible, targeted advertising could start to address this issue at the same time supporting and enhancing the role of pharmacists in helping women.

Submitted by:

Marilyn Beaumont OAM

National Board Chair

Australian Women's Health Network

[redacted]

[redacted]

31 January 2017

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

Re: MS Health application for ulipristal acetate [redacted] to be included in Appendix H.

To whom it may concern

Family Planning NSW is the leading provider of reproductive and sexual health clinical and training services in NSW with particular expertise in emergency contraception.
We welcome the opportunity to make a submission supporting the application by MSHealth Pty Ltd to list ulipristal acetate [redacted] on Appendix H as this would raise community awareness of emergency contraception and lead to improved access for women.

Background

Available data suggest that approximately 50% of pregnancies in Australia are unplanned. Increased uptake of emergency contraception is a simple and safe strategy for preventing unplanned pregnancies which simultaneously allows women to control their fertility whilst reducing health care related costs.

Since April 2016, Australian women have had access to three methods of emergency contraception:

a. Ulipristal acetate, available as a single dose tablet by private prescription since April 2016 and since 1st February 2017 as a Schedule 3 medicine (only one product available as [redacted]); licensed for use up to 5 days after unprotected intercourse.

b. Levonorgestrel emergency contraceptive pill, available as a single dose tablet since 2004 as an S3 medication (multiple brands available); licensed for use up to 3 days after unprotected intercourse.

c. Insertion of a copper-bearing intrauterine device (IUD) within 5 days of unprotected intercourse.

Each emergency contraceptive method has specific advantages and disadvantages as documented in the Family Planning NSW Information Sheet for consumers available at: https://www.fpnsw.org.au/health-information/contraception/emergency-contraception.

We believe that women seeking advice at a pharmacy or other clinical service about emergency contraception should be provided with evidence-based information about their options in order to make the best possible choice for themselves.

[redacted]
[redacted]

Support for inclusion of UPA in Appendix H

Despite the public health benefits of emergency contraception, Australian research has shown that awareness and knowledge about emergency contraception is low. Advertising UPA to the public has the potential to increase awareness not only of UPA but of emergency contraceptive options as a whole. For women making a decision to use emergency contraception following unprotected intercourse, contraceptive failure or sexual assault, timely access is essential in order to maximise effectiveness. Inclusion of UPA within Appendix H has the potential to not only raise general awareness of emergency contraception but also to facilitate this timely access.

While this would be the first emergency contraceptive pill to be included in Appendix H to date, extensive international experience of advertising this product to consumers has not been found to be associated with any adverse consequences and women will still need to interact with trained experienced pharmacy professionals when seeking emergency contraception. Pharmacists are well trained in providing evidence-based information and advice to support women's choices and well supported through their professional networks, with additional training provided by organisations such as Family Planning NSW. Women themselves are supported in making the best choice for their individual situation through publically available information on reputable websites including those from family planning organisations in all states and territories.

In summary

While the down-scheduling of levonorgestrel and ulipristal acetate emergency contraceptive pills has been significant in improving timely access to emergency contraception, inclusion of ulipristal acetate in Appendix H is an important next step in the prevention unplanned pregnancies. This inclusion will significantly increase women's ability to exercise control in the management of their own reproductive and sexual health.

For further information, please contact:- Dr Deborah Bateson deborahb@fpnsw.org.au

Yours sincerely

[redacted]

Adj. Prof Ann Brassil
CEO
Family Planning NSW

REFERENCES

Calabretto H 2009 Emergency contraception - knowledge and attitudes in a group of Australian university students. *Australian and New Zealand Journal of Public Health*. 33(3): 234-239

Hussainy SY, Ghosh A, et al. Protocol for ACCESS: a qualitative study exploring barriers and facilitators to accessing the emergency contraceptive pill from community pharmacies in Australia. *BMJ Open* 2015; 5:e010009. www.dx.doi.org/10.1136/bmjopen-2015-010009

Mazza D, Harrison CM, et al. Emergency contraception in Australia: The desired source of information versus the actual source of information. *Medical Journal of Australia* 2014; 200(7):414-5

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Trussell J, Calabretto H 2005 Cost savings from use of emergency contraceptive pills in Australia. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 45:308-311

FPNSW factsheet on emergency contraception: https://www.fpnsw.org.au/health-information/contraception/emergency-contraception.

From: [redacted]
To: Medicines Scheduling
Subject: MS Health application for Ulipristal inclusion in Appendix H [SEC=No Protective Marking]
Date: Tuesday, 7 February 2017 2:21:14 PM

To _ Medicine Scheduling
TGA
Canberra

I am writing to support the application of MS Health for inclusion of Ulipristal in Appendix H. Ulipristal for use as Emergency Contraception(EC) is a significant addition to the drugs already available as EC and sold OTC. As an obstetrician and gynaecologists I am aware that the accessibility and indeed the existence of EC is not nearly as widely known among people of reproductive age as it should be, and I support all efforts to increase the community's knowledge of EC and its availability.

[redacted]

[redacted]

[redacted]

Australian Self-Medication Industry Ltd.
[redacted]

9 February 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au

Dear Sir or Madam,

Notice inviting public submissions under Reg 42ZCZK of the *Therapeutic Goods Regulations* 1990 Scheduling proposals to be considered at the ACMS Meeting, March 2017

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and would like to provide comment on four of the scheduling proposals that will be referred to the March 2017 meeting of the ACMS.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates the opportunity to provide public comment in relation to ACMS agenda scheduling proposals. We wish to address relevant matters under section 52E of the *Therapeutic Goods Act* 1989.

Please find enclosed, under cover of this letter, ASMI's comments in relation to the following scheduling proposals that will be considered by the ACMS at the March 2017 meeting:

Ibuprofen

> *A request has been made to amend the Schedule 3 entry for ibuprofen to include a modified release oral dose form of 600 mg of ibuprofen per dosage unit in packs of 32 or less dosage units when labelled: a. with a recommended daily dose of 1200 mg or less of ibuprofen and, b. not for the treatment of children under 12 years of age and include ibuprofen 600 mg in modified release dosage form in Appendix H.*

[redacted]

Loratadine

> *A request has been made to exempt from scheduling loratadine 10 mg or less in divided preparations for oral use in packs containing not more than 5 dosage units when used in children 6 -12 years of age for the treatment of seasonal allergic rhinitis.*

Each of these agenda items is presented as a separate attachment.

As an industry representative, ASMI is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

[redacted]
[redacted]

Agenda item 3 - Ibuprofen

> *A request has been made to amend the Schedule 3 entry for ibuprofen to include a modified release oral dose form of 600 mg of ibuprofen per dosage unit in packs of 32 or less dosage units when labelled: a. with a recommended daily dose of 1200 mg or less of ibuprofen and, b. not for the treatment of children under 12 years of age and include ibuprofen 600 mg in modified release dosage form in Appendix H.*

Introduction

ASMI supports the proposal to amend the Schedule 3 entry for ibuprofen to include a modified release product containing 600mg of ibuprofen per dosage unit.

ASMI supports the inclusion of modified release ibuprofen in Appendix H to allow direct to consumer advertising for the product covered by the proposed Schedule 3 entry.

ASMI Comment – S3

ASMI understands that the scheduling proposal relates to a twice daily modified release product and that the total daily dose of ibuprofen from the modified release product will be identical to the total daily dose from the existing immediate release products containing 200mg and 400mg of ibuprofen.

In Australia, ibuprofen has been a schedule 2 medicine for more than 20 years and (in some cases) has been exempted from scheduling for more than 10 years.

The safety profile of immediate release ibuprofen is well characterised.

ASMI understands that the safety profile of the 600mg modified release product is comparable with the safety profile of the 200mg immediate release dosage form.

ASMI notes that the availability of a modified release ibuprofen product will provide an alternative option to the existing immediate release ibuprofen products.

ASMI notes that:

- Immediate and modified release options for naproxen are included in Schedules 2 and 3.
- Immediate and modified release options for paracetamol are exempt from scheduling or included in Schedule 2
- Immediate release options for diclofenac are included in Schedules 2 and 3.

All of these immediate and modified release options can be advertised to consumers (either through inclusion in Appendix H, through inclusion in Schedule 2, or through exemption from scheduling).

ASMI Comment – Appendix H

ASMI believes that raising public awareness of Schedule 3 medicines will deliver a range of benefits – firstly for consumers by increasing awareness of a broader range of therapeutic options; secondly, for pharmacists by promoting their professional role in managing conditions for which Schedule 3 medicines are available.

The TGA Schedule 3 Advertising Guidelines (dated November 2000) refer to the following criteria that should be used when determining suitability of a medicine for inclusion in Appendix H. These include:

- Potential public health benefit
- Likelihood of advertising leading to inappropriate patterns of use
- Provisions relating to the Therapeutic Goods Advertising Code
- Whether the entry may result in advertising of goods for an indication other than those included in the ARTG
- Ability of the consumer to appropriately use through labelling / CMI etc.

ASMI believes that modified release ibuprofen fulfils the above criteria. In Australia, ibuprofen has been a schedule 2 medicine for more than 20 years and as a substance has been able to be advertised for that time (with some ibuprofen products having been exempted from scheduling for more than 10 years). This has not led to inappropriate use or misuse among consumers.

The new Schedule 3 product is a twice per day modified release dosage form. ASMI believes that there is a potential public health benefit in raising the awareness of consumers to an additional pain relief option that offers an easy to follow dosage regimen. The availability of the pharmacist at the point of sale means that consumers will be made aware verbally, in addition to product labelling, of the twice daily dosing of this product.

It is important for consumers to be aware of additional pain relief options that are easy to use and have a favourable safety profile.

There is very little likelihood that advertising of a modified release ibuprofen dosage form will lead to inappropriate patterns of use. Ibuprofen has been an advertisable substance for many years and advertising this particular product is not expected to alter the benefit vs risk profile that currently exists.

Consumers are familiar with the use of similar analgesics such as aspirin, paracetamol and naproxen, as well as existing Schedule 2 and unscheduled ibuprofen. The TGA Medicines Advisory Statement Specifications contain the required warning statements that allow consumers to use the product appropriately. These statements clearly state the precautions and contraindications. The involvement of pharmacists with supply of the product will also help ensure that it is used appropriately by people for whom it is not contraindicated.

Consumers have been managing the short term relief of muscular aches and pains, mild to moderate pain, dental pain, and period pain in an appropriate manner and this is not expected to change with advertising of a modified release form of ibuprofen. This group of indications is established as being suitable for management with OTC medicines and is not likely to be conflated with the indications of any prescription only medicines.

It should also be noted that none of the above indications are “prohibited representations” or “restricted representations” listed in Appendix 6(1) and 6(2) of the Therapeutic Goods Advertising Code and should therefore be considered as suitable for advertising.

As with all Schedule 3 medicines, the labelling of the product is approved by the TGA and a Consumer Medicines Information document will be available from pharmacists in order to assist consumers.

Conclusion – S3

On the basis of ibuprofen’s well characterised safety profile and for consistency with other comparable analgesic substances, ASMI supports the proposed inclusion of a modified release product in the Schedule 3 entry for ibuprofen.

Conclusion – Appendix H

ASMI supports the proposal to include ibuprofen in Appendix H, and believes that there are benefits for both consumers and pharmacists with increasing awareness of Schedule 3 medicines in general.

Ibuprofen, as a substance, has been advertisable for more than 20 years as a Schedule 2 product. ASMI believes that there are potential public health benefits in advertising the Schedule 3 product to consumers, who could benefit from more options for relief of pain.

The advice from the pharmacist, together with appropriate warning statements on labelling and the availability of the CMI will help ensure that consumers have the information they need to manage the use of this product for the short term relief of pain.

Agenda item 3 - Loratadine

A request has been made to exempt from scheduling loratadine 10 mg or less in divided preparations for oral use in packs containing not more than 5 dosage units when used in children 6 -12 years of age for the treatment of seasonal allergic rhinitis.

Introduction

Currently loratadine is exempt from scheduling when in primary packs containing 10 dosage units or less, labelled with a recommended daily dose not exceeding 10 mg of loratadine, when used for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over.

ASMI supports the proposal to exempt from scheduling packs of 5 dosage units when used for the treatment of seasonal allergic rhinitis in children 6 to 12 years of age.

ASMI Comment

The symptoms of seasonal allergic rhinitis will be easily identified by consumers and treatment of the symptoms using second generation antihistamines can be safely managed by consumers without the need for healthcare professional intervention.

Loratadine is an effective first line treatment for the symptoms of seasonal allergic rhinitis and has been available as an unscheduled medicine in Australia since 2012 in small packs to help manage a minor self-limiting condition without the intervention of a healthcare professional.

The safety of loratadine is well established with over 20 years of product use in Australia and internationally, including use in children as young as 12 months of age. ASMI understands that there has been no evidence of misuse or abuse when available as a Schedule 2 or unscheduled medicine.

Allergic rhinitis significantly impacts the health and quality of life in children and the diagnosis and treatment of allergic rhinitis in children over 2 years of age follows essentially the same pattern as that in adults (children younger than 2 years may be referred to an allergist/immunologist for diagnosis and subsequent management).

To date in Australia, second generation non-sedating antihistamines are only available for children 12 years and over outside of pharmacies. This leaves a range of efficacious and safe options unavailable for children under 12 years of age other than via pharmacy. This is inconsistent with similar markets such as the UK and the USA where these products have been freely accessible outside of pharmacies for children 2 years and over for more than 10 years.

With a long history of use in young children in Australia, access to loratadine only via pharmacy for children under 12 years of age presents a gap in access for affected children and their carers.

Loratadine is generally safe for use in children 12 months of age and older. The types and frequencies of adverse events reported in children are consistent with those reported in adults with no increased risks identified in children. ASMI understands that the availability of unscheduled loratadine products in Australia since 2012 has not resulted in any safety concerns.

Given the well-established safety profile of loratadine, and the very low risk of misuse and inappropriate use, ASMI considers that an unscheduled pack size of 5 dosage units of loratadine for

children 6-12 years of age presents minimal risk to children while increasing the availability of an efficacious second generation non-sedating antihistamine.

In markets with a similar regulatory system to Australia such as the UK and the USA, loratadine has been available for many years for children as an unscheduled medicine at a much younger age (2 years and over) with wider therapeutic indications (seasonal allergic rhinitis, perennial allergic rhinitis and chronic urticaria) with either no pack size restrictions or in larger pack sizes than in Australia. In the USA, loratadine in both solid and liquid forms is approved in OTC medications (equivalent to unscheduled medicines in Australia) for children 2 years and over without any pack size limitations. In the UK both solid and liquid forms of loratadine have been approved for children 2 years and over in large pack sizes (tablets 30 packs; liquids 70 mg) since 2012.

Conclusion

On the basis of loratadine's safety profile and for consistency with other similar markets, ASMI supports the proposed exemption from scheduling for packs containing not more than 5 dosage units when used in children 6-12 years of age.

[redacted]

9 February 2017

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

Dear Committee,

Re: Inclusion of Ulipristal in Appendix H

[redacted] is a [redacted] statewide women's health promotion, information and advocacy service. We work collaboratively with health professionals, policy makers and community organisations to influence and inform health policy and service delivery for women.

[redacted] believes that direct consumer advertising of ulipristal 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.[1]

Direct advertising can have important direct and indirect benefits for public health by increasing community knowledge of the availability of this simple, safe and effective option for preventing unplanned pregnancy. It is important that women are supported to exercise choice and control in the management of their own health, particularly in regards to Emergency Contraception which can be a personal and sensitive area.

We do not believe that the advertising of ulipristal will lead to inappropriate patterns of medication use because for the following reasons: ulipristal will remain in Schedule 3 meaning a pharmacist continue to be personally involved in every sale; the pack contains a single tablet so the potential for inappropriate or incorrect use is very low; and advertising will emphasise the role of pharmacists in advising women on its correct and appropriate use.

[1] Hall C, Millner P. Advertising emergency contraception using local radio: an evaluation. Health Education Journal

[redacted]

[redacted] supports:
• the direct advertising of Ulipristal 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]

INCLUSION OF ULIPRISTAL ON APPENDIX H

CHILDREN BY CHOICE SUBMISSION TO THE THERAPEUTIC GOODS ADMINISTRATION

FEBRUARY 2017

[redacted]

ABOUT CHILDREN BY CHOICE

We are a non-profit community organisation providing counselling, information and education services on all options with an unplanned pregnancy, including abortion, adoption and parenting.

We provide a Queensland-wide telephone counselling, information and referral service to women experiencing unplanned pregnancy. We deliver sexual and reproductive health education sessions in schools and youth centres, and offer training for health and community professionals on unplanned pregnancy options. We advocate on women's sexual and reproductive health issues at a state and federal level, and support access to all options with an unplanned pregnancy, including abortion.

In 2015-16 we received a total of 4597 contacts from over 1700 women, ranging in age from 12 to over 50. We also saw over 86,000 visitors to our website, delivered sexuality education to 394 young people and provided training to over 2650 professionals.

We are the only independent, not-for-profit women's service dedicated to unplanned pregnancy in Australia. As an organisation, we have over 40 years' experience in unplanned pregnancy and reproductive choice. We have supported over 200,000 women during this time with decision-making counselling, accurate information about their options, referrals to health services and community organisations, post-abortion support, and/or financial assistance to access abortion and contraceptive services.

We are a pro-choice, all options, woman-centred service. We support and trust women to make the best decision they can with an unplanned pregnancy, for themselves and their families. Women are the experts in their own lives. Nobody else can know better than the pregnant woman herself what is best for her in her situation.

CONTACT

Pamela Doherty
Education and Training Coordinator
Children by Choice
[redacted]
[redacted]

COMMENTS

It is estimated that almost half of all pregnancies in Australia are unplanned[1] . 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 after unprotected sex.

Children by Choice is supportive of measures to increase women's access to more effective contraception methods including the ability to access timely and accurate information about emergency contraception, namely ulipristal, to reduce the number of unplanned pregnancies in Australia.

For women to truly possess reproductive autonomy they need to be equipped with good knowledge and information. The inclusion of ulipristal in Appendix H is an important step to support this.

KEY CONSIDERATIONS FOR LISTING ULIPRISTAL ON APPENDIX H

Children by Choice supports the Public Health Association's policy on contraception, which is very clear on the public health benefits of both access to contraception and awareness of contraception, particularly Emergency Contraception (EC).

Advice and provision of contraception is an essential health service and is cost effective in reducing the impact of unintended pregnancies on individuals and the health system. All potentially sexually active people who are capable of becoming pregnant or causing pregnancy should be provided with accurate information about all contraceptive options and have access to whichever method is both medically suitable and acceptable to them.

There is much misunderstanding about the role, safety, timing, mechanism of action and accessibility of EC within the general community. [2] [3] There is a need for increased training and awareness of Long Acting Reversible Contraception (LARC) and Emergency Contraception (EC).[4]

Ulipristal is more effective than levonorgestrel, especially when taken within the first 24 hours after Unprotected Sexual Intercourse (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. [5]

To ensure women have the best chance of preventing a pregnancy access to this accurate information is necessary. Improving access to information and education about EC will increase women's uptake of EC to allow them to prevent a pregnancy. The likelihood of "inappropriate use" would be minimised with comprehensive training with the pharmacy sector and education with women. Trusting women to make their own decisions about their reproductive health also removes the notion of "inappropriate use".

It is also important to note that EC IS extremely safe, even when used repeatedly. Compared with the potential health risks of pregnancy, taking ECPs to prevent unintended pregnancy is much safer. Women should be able to access and use EC as many times as they need. However, ongoing methods of contraception are more effective than ECPs[6]

The recent decision by the TGA to reschedule ulipristal is applauded and we urge the TGA to continue to support women's reproductive autonomy by listing ulipristal on Appendix H.

[1] 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.

[2] Weisberg E, Fraser IS. Knowledge and use of emergency contraception among women seeking termination of pregnancy in New South Wales. Med J Aust 1997; 166: 336

[3] Calabretto H, Emergency contraception – knowledge and attitudes in a group of Australian university students. Australian and New Zealand Journal of Public Health. Volume 33, Issue 3, pages 234–239, June 2009

[4] Public Health Association of Australia: Policy-at-a-glance – Contraception Policy, Sept 2014. Sourced online

[5] 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*

[6] *The International Consortium on Emergency Contraception*, Repeated use of emergency contraception pills: The facts, October 2015. Soucre online

From:	Tim Bavinton
To:	Medicines Scheduling
Cc:	[redacted]
Subject:	Family Planning Alliance Australia support for MSHealth application for UPA EC listing in Appendix H of TGA registry [SEC=No Protective Marking]
Date:	Thursday, 9 February 2017 5:32:10 PM

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

Re: MS Health application for ulipristal acetate [redacted] to be included in Appendix H

To whom it may concern

Family Planning Alliance Australia (FPAA) is the nation's peak body in reproductive and sexual health. It promotes advances in public health through policy insights and advocacy and represents the leading health and education agencies across Australia.

FPAA supports the listing on Appendix H of all types of approved emergency contraception. For this reason, we support the application by MSHealth Pty Ltd to list ulipristal acetate [redacted] on Appendix H, as it would raise community awareness of emergency contraception and lead to improved access for women.

Background

Increased uptake of emergency contraception, regardless of brand, has the potential to prevent unintended pregnancies thereby contributing to the reduction of costs to the health care system.[1] Ulipristal acetate (UPA) has been available by private prescription since April 2016 and from 1 February 2017 as a Schedule 3 medicine. Currently there is only one UPA emergency contraception product available in Australia. Other methods of emergency contraception include a single dose levonorgestrel (LNG) emergency contraceptive pill, available since 2004 as an S3 medication, and insertion of a copper-bearing intrauterine device (IUD) within 5 days of unprotected intercourse. Each emergency contraceptive method has relative advantages and disadvantages and FPAA believes that women should be provided with evidence-based information about all options when seeking advice at a pharmacy or other clinical service.

Inclusion of UPA in Appendix H

To date in Australia, there has been no emergency contraceptive product included in Appendix H. Research has identified that overall knowledge about emergency contraception could be improved in Australia.[2-5] Whilst the down-scheduling of LNG and UPA emergency contraceptive pills have addressed many of the issues related to improved emergency contraception access, lack of community awareness will limit its uptake. There is evidence from the United States that direct-to-consumer media campaigns in print, radio, television and outdoor venues have resulted in increased knowledge about emergency contraception. In the majority of countries where emergency contraception is available without prescription, it is advertised directly to the public without any known adverse consequences.

In Australia, inclusion of UPA and LNG in Appendix H would support improved awareness and uptake of all methods of emergency contraception as women still need to interact with a trained pharmacist in order to access it. Information to consumers would complement other sources of information and education about emergency contraception by family planning and other

evidence-based organisations across Australia through their printed and web-based resources and the education and training programs for both health professionals and the community.

We are confident that pharmacists, as the primary front-line providers of emergency contraception, will have the required training and professionalism to provide women with information to make the most appropriate choice for their individual situation. Given that pharmacists are also well placed to provide evidence-based information about the most effective methods of long term contraception, inclusion of [redacted] in Appendix H has the potential to improve overall contraceptive uptake in the community.

Conclusion

FPAA believe strongly that women should be able to have access to information on the different forms of emergency contraception. Medically approved and evidence-based advertisement of the different forms of contraception can improve awareness of contraceptive options, and have a direct reproductive health benefit for women. FPAA does not advocate for any particular brand or method of emergency contraception. The application by MSHealth Pty Ltd to list ulipristal acetate is supported as it has the potential to raise awareness about emergency contraception for women and also contribute to the public health perspective in reducing unintended pregnancies in Australia. FPAA would support a similar application by the pharmaceutical companies producing levonorgestrel (LNG).

While the down-scheduling of both levonorgestrel and ulipristal acetate has been significant in improving timely access to emergency contraception, this next step with further support women's ability to control their fertility.

For further information, please contact the FPAA Board via:

Secretariat

Family Planning Alliance Australia (FPAA)

[redacted]

Yours sincerely

Tim Bavinton

on behalf of FPAA Board

REFERENCES

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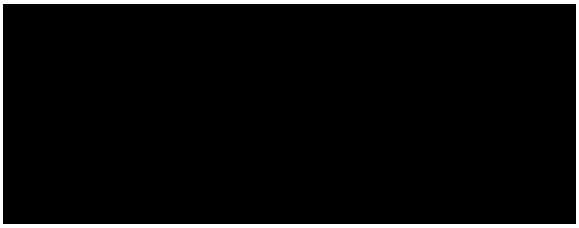

6 February, 2017

Medicines Scheduling Secretariat
Therapeutic Goods Administration
medicines.scheduling@tga.gov.au

Proposal: To add [redacted] (ulipristal) to the Appendix H registry, enabling the promotion of [redacted] (ulipristal) and the benefits of emergency contraception, directly to women.

Medicines Scheduling Secretariat,

Reproductive Choice Australia (RCA) was formed in 2005 and is Australia's only dedicated pro-choice advocacy organisation, campaigning on local, state and national issues. We are a non-partisan, not-for-profit organisation run entirely by volunteers. Our purpose is to advocate for the promotion, maintenance, extension and improvement of access to the full range of reproductive health care services including but not limited to:

- all forms of contraception including emergency contraception
- medical and surgical abortions
- evidence based, unbiased information and counselling in relation to pregnancy options
- respect for women's bodily autonomy
- unhindered medical decision-making
- appropriate legal frameworks governing abortion

Emergency contraception (EC) is crucial to many Australian women, who strongly desire control over their own reproductive choices at every stage. It is imperative that women who use EC are well informed on the benefits and health information, aware of the range of options available to them, and able to access this medication easily and quickly. In Australia, there are currently 3 forms of EC available:

- a single dose of levonorgestrel, licensed for use up to 3 days after unprotected sex and available over-the-counter, with an estimated 85% efficacy at preventing pregnancy
- or a single dose of ulipristal acetate, licensed for up to 5 days after unprotected sex and available over-the-counter, with a significantly higher efficacy than levonorgestrel and a longer window of time
- insertion of an intrauterine device within 5 days of unprotected sex, available through a GP and with the highest effectiveness at preventing pregnancy

Given its superiority to levonorgestrel and the longer time-frame of effectiveness, RCA was glad to see that [redacted] (ulipristal) is now available over-the-counter in Australia. This will make ulipristal acetate significantly easier for women to access quickly.

We appreciate the opportunity to comment on MS Health's proposal to add E[redacted] (ulipristal) to the Appendix H registry, thus allowing [redacted] (ulipristal) to be advertised directly to women.

We believe that direct advertising would further extend access and give Australian women important information. In particular, the knowledge that [redacted] (ulipristal) can be used up to 5 days after intercourse, with a significantly higher efficacy than that of levonorgestrel is extremely valuable to women when making decisions about their options for preventing pregnancy. Advertising of [redacted] (ulipristal) would allow information on the safety, effectiveness and availability of EC to be given directly to women to inform their decisions, while also highlighting the role of pharmacists in being a source of help. Informative advertising would allow women to plan ahead, before EC is even needed. Importantly, it may also allow women in remote areas or with privacy concerns to buy it online or over the phone and have it delivered in case they need it urgently one day.

We believe that MS Health has provided information in line with the factors for inclusion of a substance in Appendix H. In reference to the factor of public health benefits, direct and responsible advertising would do much to combat the reported lack of knowledge on availability, safety and effects of EC among Australians. This would impact women's safe use of EC, assist in avoiding unwanted pregnancies and consequent abortions.

We note that MS Health is committed to providing pharmacists and users of [redacted] (ulipristal) with accurate, detailed health information, including on pharmacy dispensing software, pack inserts and their company website. This ensures women have multiple points of access to all the information they require before using [redacted] (ulipristal). This information, and instruction on correct use, would be aided by advertising discussed with pharmacists.

Finally, there is very low likelihood that advertising would lead to inappropriate use, as [redacted] (ulipristal) is only available in single doses, would require pharmacist contact to obtain and will be advertised with an emphasis on the necessity of pharmacist advice; nor will it be advertised for any other purpose. Their emphasis on the role of pharmacists, and MS Health's recognition of the importance of educating, collaborating with and supporting pharmacists, demonstrate compliance with the wider regulatory system and advertising codes.

We support the proposal to add [redacted] (ulipristal) to the Appendix H registry.

Yours sincerely,

Sarah Reynolds
Vice-President
On behalf of the committee and members of Reproductive Choice Australia

8/02/17

Medicines Scheduling Secretariat
Medicines Scheduling
Therapeutic Goods Administration
Department of Health, PO Box 100
Woden, ACT, 2606, Australia
Medicines.Scheduling@tga.gov.au
www.tga.gov.au

To whom it may concern:

Re: Application for inclusion of ulipristal acetate on Appendix H

CRANAplus is the peak professional body for remote & isolated health professionals. For over thirty years CRANAplus has provided education, support and professional services for the multi-disciplinary health workforce providing healthcare services in remote and isolated areas of Australia. We provide advice to Government, service providers, clinicians, and consumers on equitable access to safe high quality health services.

CRANAplus supports MS Health's submission that further to the re-scheduling of [redacted] (ulispristal acetate) that it be included within the Appendix H registry thus enabling broader knowledge and understanding of this medication to the health benefit of women.
Pharmacists have a key role in providing Public Health Information and with this inclusion, an increased awareness through specific for use, targeted and responsible advertising will result in greater knowledge and awareness of the target group regarding the use of this drug only for which it is approved, as a Schedule 3 Pharmacy Only Medicine.

In our submission in May 2016 CRANAplus advised the Advisory Committee on Medicine Scheduling (ACMS) of its support for that proposed amendment of ulipristal acetate to be listed as a Pharmacy Only Medicine (Schedule 3) for emergency contraception, and note that subsequent amendment.

We take this opportunity to reinforce our key points in relation to access to medicines for remote consumers as part of a Quality Use of Medicines
Given that, the remote context is unique and accessibility to services can be problematic.

With limited pharmacists available across the remote and isolated areas of Australia to dispense and supply ulipristal acetate to women within these communities, nurses, midwives and nurse practitioners, being the predominate workforce, are able to supply medications according to

[redacted]

[redacted]

protocol or prescribing.

In relation to this submission regarding the inclusion within the Appendix H registry, we advocate that the advertising must be appropriate for that remote sector, a standard advertising campaign or resources not adapted to the remote population will potentially be ineffective.

- The advertising of the product, as for the information sheet {pamphlet} accompanying the medication, is written in a clear, culturally appropriate manner, to be understood by the recipient that the medication is an emergency contraception. Specific information to be provided to women who are breastfeeding to seek advice or referral to a Lactation Consultant.
    - In addition we reiterate that:
- Expansion of the list of health professionals inclusive of remote area nurses, midwives and nurse practitioners to supply the ulipristal acetate to women in remote and isolated areas.
- All education and training providers of health professionals embed ulipristal acetate product information and client education into their sexual and reproductive health curriculums.
- Ensure evidence based guidelines used by remote health professionals i.e. Primary Clinical Care Manual and CARPA Manual are inclusive of the administration and management of ulipristal acetate medication.

We would be very pleased to provide any further clarification of points made in this supporting letter.

Yours Sincerely,

[redacted]

Geri Malone
Director of Professional Services
CRANAplus
[redacted]

[redacted]

[redacted]

8 February 2017

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

To whom it may concern

Re: MS Health application for ulipristal acetate [redacted] to be included in Appendix H

Family Planning Victoria (FPV) provides broad based reproductive and sexual health clinical and educational services. We are the leading provider of education to doctors and nurses in Victoria and have been active in working with pharmacies over the provision of over the counter levonorgestrel emergency contraception.

FPV supports the application by MS Health Pty Ltd to list ulipristal acetate ([redacted]) on Appendix H, as it would raise community awareness of emergency contraception and lead to improved access for women.

Oral emergency contraception including ulipristal acetate (UPA) is safe. UPA appears to be more effective than oral levonorgestrel emergency contraception and remains effective for up to 120 hours after unprotected sex.[1] There are no strong or absolute contraindications to its use.[2] Increased uptake is extremely unlikely to lead to unwanted health consequences. Easier access to emergency contraception has been shown to increase uptake but has not been shown to lead to an increase in behaviour that might increase the risk of sexually transmitted infections. Women who use emergency contraception are no less likely to use more effective methods of contraception than other women.[3]

While in Australia, knowledge of the exitance of oral emergency contraception is high, knowledge about access and actual uptake is low.[4-7] Most episodes of unprotected sex are not followed by emergency contraception. A recent analysis in the USA showed women had an average of 18 episodes of unprotected sex prior to an unintended pregnancy.[8] Inclusion of ulipristal acetate (UPA) in Appendix H and direct marketing to consumers has the potential to increase uptake and to reduce unintended pregnancy.[9]

Cost can be a considerable barrier to accessing emergency contraception. Advertising has the potential to increase women's awareness that they can access oral emergency contraception without the inconvenience and cost associated with a doctor's visit.

In the majority of countries where emergency contraception is available without prescription, it is advertised directly to the public without any known adverse consequences.

[redacted]

[redacted]

Conclusion

FPV believe that direct to consumer advertising of [redacted] is likely to increase consumer awareness and subsequently uptake of emergency contraception. It has the potential to reduce unintended pregnancies. Direct marketing is unlikely to have adverse consequences.

For further information, please contact: Dr Kathleen McNamee on [redacted].

Yours sincerely,

[redacted]

[redacted]

Chief Executive Officer

Dr Kathleen McNamee
Medical Director

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[redacted]

From:	glynis
To:	Medicines Scheduling
Subject:	Public submission Appendix H Application [SEC=No Protective Marking]
Date:	Friday, 10 February 2017 2:32:35 PM

Women's Health Tasmania is a statewide community based health promotion charity. We recognise the World Health Organisation's definition of Health "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity". Our framework of practice is based upon the social determinants of health of which gender is considered to be a major factor in poor health outcomes in Australia and Internationally. Reproductive issues present a barrier to full participation for some women and the ability to regulate their fertility through contraception is vital to their equity and opportunities. Tasmania has a high proportion of socio-economic disadvantage and the highest proportion of single mothers after the Northern Territory. Access to contraception is vital. Sadly Tasmanians also have poorer literacy and poorer health literacy than most States. Women's Health Tasmania supports advertising and promoting Ulipristal - [redacted]. There is considerable ignorance about this valuable advance in contraception and many Tasmanian women have misconceptions about its use, especially the time period of its effective use. It is also not widely understood by pharmacists and other practitioners.
We understand the Australian Women's Health Network, of which we are a member, has made a clear and concise explanation of the need for both promotion through advertising and the required education for professionals.
We support their submission and commend all of their recommendations to the Therapeutic Goods Administration.
Please contact me if you require any further information.
Glynis Flower
CEO
Women's Health Tasmania
[redacted]

[redacted]

Office of the President
Professor Steve Robson

[redacted]

10 February 2017

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

By email: Medicines.Scheduling@tga.gov.au

To whom this may concern

Re: MS Health application for [redacted] (ulipristal) inclusion in Appendix H

I am writing in relation to MS Health's application to the Australian Committee on Medicine Scheduling (ACMS) to have [redacted] (ulipristal) added to the Appendix H registry.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) is a not-for-profit entity that delivers education and training programs in the specialist discipline of obstetrics and gynaecology (O&G), and is the lead standard-setting body for women's health in Australia and New Zealand. The College represents more than 2000 Fellows (O&G Specialists), as well as trainees and general practitioners (Diplomates).

RANZCOG is aware that knowledge about emergency contraception is low amongst women in Australia and strongly believes that women should have access to information on the different forms and brands of emergency contraception available. This information would potentially help women avoid unintended pregnancies. As such, RANZCOG supports MS Health's request to responsibly promote [redacted] (ulipristal) and the benefits of emergency contraception directly to women.

The College further notes that direct-to-consumer advertising of emergency contraception products is currently permitted in many other countries.

Please do not hesitate to contact [redacted], Director, Practice and Advocacy ([redacted]; E: [redacted] should you require further information or wish to discuss this submission.

Yours sincerely,

[redacted]

Professor Steve Robson
President